IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

STEPHEN KEARNEY, Derivatively on Behalf of CASSAVA SCIENCES, INC., Plaintiff, v. REMI BARBIER, LINDSAY BURNS, ERIC J. SCHOEN, JAMES W. KUPIEC, MICHAEL MARSMAN, RICHARD J. BARRY, ROBERT Z. GUSSIN, MICHAEL J. O'DONNELL, SANFORD R. ROBERTSON, and PATRICK J. SCANNON, Individual Defendants, -and- CASSAVA SCIENCES, INC., a Delaware Corporation, Nominal Defendant.	Case No. 1:23-cv-1353 JURY TRIAL DEMANDED

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

Plaintiff Stephen Kearney ("Plaintiff"), by his undersigned attorneys, derivatively and on behalf of Nominal Defendant Cassava Sciences, Inc. ("Cassava" or the "Company"), files this Verified Shareholder Derivative Complaint against Individual Defendants Remi Barbier, Lindsay Burns, Eric J. Schoen, James W. Kupiec, Michael Marsman, Richard J. Barry, Robert Z. Gussin, Michael J. O'Donnell, Sanford R. Robertson, and Patrick J. Scannon (collectively, the "Individual Defendants" and with Cassava, "Defendants") for breaches of their fiduciary duties as directors and/or officers of Cassava, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, violations of Section 14(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and for contribution under Sections 10(b) and 21D of the Exchange Act. As for his complaint against the Individual Defendants, Plaintiff alleges the following based upon

personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, a review of United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Cassava, legal filings, news reports, securities analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a shareholder derivative action that seeks to remedy wrongdoing committed by Cassava's directors and officers from September 14, 2020 through July 26, 2022, both dates inclusive (the "Relevant Period").

2. Cassava is a Delaware biotechnology corporation based in Austin, Texas, that develops drugs for neurodegenerative diseases. Its lead therapeutic product candidate is "simufilam" which was developed for the purpose of treating Alzheimer's disease ("Alzheimer's"). The Company's lead investigational diagnostic product is "SavaDx," a blood-based diagnostic test created for the purpose of detecting Alzheimer's.

3. Before beginning development on simufilam, Cassava was almost entirely focused on developing Remoxy, a gel form of the opioid oxycodone. From 2002 to 2018, Cassava (then named Pain Therapeutics) faced continuous hurdles from the United States Food and Drug Administration ("FDA") in getting Remoxy approved. In 2018, Remoxy was rejected for a fourth time by the FDA, effectively killing the Company's chance of bringing the drug to market and thereby making the Company vulnerable to financial crisis.

4. In an effort to save the Company, Cassava shifted its focus away from Remoxy and towards the development of simufilam. Although Alzheimer's medications are notoriously difficult to test and produce, and although the Company admitted to having had "no history of product approvals" for any type of drug, simufilam was believed to be Cassava's golden parachute. Indeed, following the FDA's rejection of Remoxy, the Company's very existence was now entirely dependent on the success of simufilam. As Chief Executive Officer ("CEO") Remi Barbier put it, "we're a moonshot with one rocket ship."

5. Simufilam is a unique Alzheimer's medication because it aims to both treat the symptoms of Alzheimer's and to cure the disease. Simufilam targets filamin A ("FLNA"), a protein in the brain that Cassava scientists claim is often misshaped in the brains of Alzheimer's patients. As such, repairing FLNA is theorized to improve brain health and treat neurodegeneration.

6. The Company represents that it measures simufilam's effectiveness in restoring brain health by looking at cerebrospinal fluid ("CSF") biomarkers. A biomarker is a measurable indicator used to determine whether a patient is impacted by a specific condition. To analyze CSF biomarkers, Cassava scientists would measure CSF levels before and after a patient took simufilam, with the expectation that, upon taking simufilam, the affected individual's CSF levels would decrease to a level indicative of a patient without Alzheimer's disease.

7. While the Company has big expectations for simufilam, it currently has no source of revenue. Therefore, Cassava's overall financial success is largely dependent upon successfully getting regulatory approval for simufilam in order to get it to market.

8. On May 15, 2020, prior to the start of the Relevant Period, the Company announced through a press release (attached to a Form 8-K filed with the SEC) that its Phase 2b study of

simufilam failed to meet its primary endpoint measurements of biomarkers. A Phase 2b study is used to assess the efficacy and side effects of a drug. As such, a drug's poor performance during a Phase 2b study would spell disaster for the drug's FDA approval. Cassava's Phase 2b study revealed that simufilam was failing to increase patients' biomarkers, which the Company represented to indicate that the drug was not successfully treating Alzheimer's. The Company announced, however, that it would conduct a "reanalysis" of the Phase 2b study data.

9. On this news, the Company's stock price dropped from a price per share of $8.11 at the closing of trade on May 14, 2020, to a price per share of $2.12 at the closing of trade on May 15, 2020.

10. On August 26, 2020, the Board of Directors (the "Board") approved the 2020 Cash Incentive Bonus Plan (the "Plan") which tied director and executive bonuses directly to share price benchmarks. In other words, pursuant to the Plan, if the Company maintained market capitalization of over $200 million for 20 consecutive business days, Company executives and board members stood to split a cash bonus pool of $10 million. The Plan was announced just weeks prior to the Company publicly announcing the positive results of its reanalysis (discussed in more detail below), which it knew would increase the Company's share value, thereby entitling Board members and executives to lucrative bonus compensation. As this Court explained in its ruling on the Motion to Dismiss in the related Securities Class Action (defined below), the suspicious timing of the Plan demonstrates the motive Board members would have had for artificially inflating the Company's stock price. (ECF 104, at 23).

11. On September 14, 2020, the Company announced in a press release that the re-analysis was successful and that simufilam demonstrated "[t]he ability to improve multiple biomarkers" in Alzheimer's patients. Defendant Barbier dismissed the initial Phase 2b results

announced in May 2020 as "serv[ing] no useful purpose." Moreover, Defendant Barbier assured investors that the re-analysis had been conducted by "outside labs."

12. On this news, shares of Cassava common stock increased from a price per share of $3.32 at the closing of trade on September 11, 2020 to a price per share of $7.75 at the closing of trade on September 14, 2020. Over the next few weeks, Cassava's stock continued to climb. By October 13, 2020, the Company's soaring stock price—which had been artificially inflated based on the false and misleading statements in the September 14, 2020 press release—allowed the Company to achieve the market capitalization milestones it had set out in the Plan, thereby providing several of the Individual Defendants with millions of dollars in bonus compensation.

13. Beginning September 14, 2020 and continuing throughout the Relevant Period, the Individual Defendants caused the Company to submit manipulated data to the FDA and made, or caused the Company to make, materially false and misleading statements to the investing public about the accuracy and reliability of the data supporting simufilam's effectiveness.

14. On November 13, 2020, the Company announced in a Form 8-K filed with SEC that it had entered into an underwriting agreement to sell 9,375,000 shares of Cassava's common stock for $75 million at a price of $8.00 per share. The Board had artificially inflated the stock price of Cassava common stock by issuing the false and misleading September 14 press release, thereby allowing it to secure a lucrative underwriting agreement—which likely would not have been available otherwise—to fund the development of simufilam and the generous bonus plan approved just months prior.

15. On February 2, 2021, the Company again announced positive research results for simufilam in a press release. Cassava revealed its open-face trial—i.e., one conducted without a placebo control group, where all patients are certain they have the drug—had shown evidence of

simufilam not only slowing or treating symptoms of Alzheimer's disease, but also restoring the cognitive ability of patients, something not yet accomplished by any Alzheimer's drug. Cautious scientists outside the Company warned, however, that open-face trials are prone to the "placebo effect," wherein improvements experienced by patients were linked to their *expectation* that the drug will have a positive effect, rather than improvements because simufilam was *working*. Despite these warnings, the Company's stock continued to soar, reaching $60.67 per share at the closing of trade on February 8, 2021.

16. On February 10, 2021, Cassava raised $200 million in a registered direct stock offering. Through the offering, the Company sold more than four million shares of its common stock at $49 per share. Cassava used this funding for simufilam's commercial development and to replenish amounts to be received by the Company's officers and directors under the Plan.

17. The truth began emerging after the market had closed on August 24, 2021 when a Citizen's Petition submitted to the FDA (the "Citizen's Petition") requested that the FDA (1) halt Cassava's Phase 3 trials of simufilam and (2) audit the Company's data and research practices. The Citizen's Petition alleged that the data Cassava was presenting on simufilam's effectiveness contained "a series of anomalies that are ***suggestive of systemic data manipulation and misrepresentation***." (Emphasis added.) In particular, the Citizen's Petition alleged that a series of Cassava's foundational pre-clinical and clinical data represented by "Western blots" showed clear signs of data manipulation and duplication. This called into question whether ***any*** data existed to support Cassava's claims of simufilam's effectiveness. Furthermore, the Citizen's Petition noted that the Company's practice of studying "Simufilam's effects in experiments conducted on ***postmortem human brain tissue*** . . . defies logic, and ***the data presented again have hallmarks of manipulation***." (Emphasis added.) The use of postmortem brain tissue was problematic because

the necessary enzymes for testing simufilam's effectiveness likely would not have survived in brains preserved at cold temperatures, yet Cassava had used such experiments to prove the drug's effectiveness.

18. The Citizen's Petition alleged that Dr. Hoau-Yan Wang ("Wang"), Cassava's principal scientific advisor and a professor at City University of New York ("CUNY") Medical School, had engaged in research misconduct by falsifying and manipulating data in a string of his published research and presentations. Some of Dr. Wang's allegedly manipulated data was central to papers used to support Cassava's claims about simufilam, leaving to question whether the drug had any scientific backing at all. Likewise, the Citizen's Petition alleged that the positive results of the Phase 2b re-analysis had not been conducted by an "outside lab," but rather by Dr. Wang. Because Dr. Wang already had a 15-year relationship with Cassava, he had conflicts of interest when performing the research for the Company. Accordingly, describing the Phase 2b re-analysis as being conducted by an "outside lab" was demonstrably false and a clear attempt by the Company to hide the fact that Dr. Wang conducted the re-analysis.

19. Moreover, the Citizen's Petition revealed that the Company had data errors in a poster it used in a July 26, 2021 presentation about its Phase 2b results at the Alzheimer's Association International Conference.

20. The next day, August 25, 2021, before the market opened, the Company issued a response, defending itself on many grounds, in part by noting that the poster used at AAIC had not been generated by Cassava, but rather by Quanterix Corp. ("Quanterix"), an independent company. As such, Cassava attempted to write off the data error as a mistake by a third party, rather than any shortcoming from the Company's own scientists.

21. Despite the Company's spin, the market received the news negatively, and the price per share of the Company's common stock dropped from $117.83 at close on August 24, 2021, to close on August 25, 2021 at $80.86. This $36.97 decline marked approximately a 31.4% one-day decrease in value.

22. The truth continued to emerge on August 27, 2021 when Quanterix issued a statement in response to Cassava, noting that "Quanterix'[s] sole responsibility with regard to this clinical study was to perform sample testing" and that "Quanterix or its employees did not interpret the test results or prepare the data charts presented by Cassava at the Alzheimer's Association International Conference (AAIC) in July 2021 or otherwise."

23. On this news, the Company's share price declined by $12.51 per share—or approximately 17.7%—from its August 26, 2021 closing price of $70.85 per share to close August 27, 2021 at $58.34 per share.

24. At the same time, research misconduct allegations against the Company intensified. On August 30, 2021, the anonymous whistleblowers filed a supplement to the Citizen's Petition that identified new instances of research misconduct.

25. On this news, the Company's share price fell from $58.34 per share at the closing of trade on August 27, 2021 to $53.26 per share at the closing of trade on August 30, 2021.

26. Dr. Elizabeth Bik, a well-respected image analyst and research investigator, learned of the allegations in the Citizen's Petition and began her own investigation into Cassava's research misconduct. Throughout the Relevant Period, on numerous occasions she would note her own concerns and additional inconsistencies prevalent in Cassava's clinical data—some of which would result in scientific journals issuing retractions on Drs. Wang's and Burns' research.

27. Cassava continued releasing false and misleading statements in an effort to protect itself from the research misconduct allegations. On September 3, 2021, Cassava issued a press release titled "Cassava Sciences Releases a Public Statement Regarding Recent Allegations." The press release contained a fierce rebuttal of the allegations by Defendant Barbier, who stated: "Let me be very clear; I think these allegations are false." Barbier, however, admitted that Cassava's presentation at the AAIC contained the visual data error that the Citizen's Petition had noted.

28. On this news, the Company's stock price fell from $54.35 per share at the closing of trade on September 2, 2021 to $50.20 per share at the closing of trade on September 3, 2021.

29. On November 4, 2021, the Company issued another press release titled "Review by Journal of Neuroscience Shows No Evidence of Data Manipulation in Technical Paper Foundational to Cassava Sciences' Lead Drug Candidate." The press release emphasized that the *Journal of Neuroscience* had requested the "raw data" of the "peer-reviewed article" and found "no evidence of data manipulation… for [Cassava's] Western blot data." A fiery Defendant Barbier remarked, "I've never doubted the integrity of our people or science… It's an important endeavor, notwithstanding pundits who may be louder than they are learned."

30. The press release and rallying cry of Defendant Barbier positively impacted the Company's stock, with it skyrocketing from a closing price of $56.66 per share on November 3, 2021 to a closing price of $84.40 on November 4, 2021. This represented a one-day price increase of $27.74 per share.

31. On November 10, 2021, Dr. Bik conducted her own review of the "raw data" that Cassava had provided the *Journal of Neuroscience* and that was made publicly available. Dr. Bik detailed on PubPeer and Twitter that the data Cassava had provided the *Journal of Neuroscience* was in fact not the original "raw data." Instead, the data was composites of cropped images.

32. On this news, Cassava's stock price fell from a closing price of $78.41 per share on November 9, 2021 to a closing price of $69.40 per share on November 10, 2021.

33. On November 15, 2021, the Company disclosed in its Form 10-Q filed with the SEC for the quarter ended September 30, 2021 that the Company had been "asked… to provide [certain government agencies] with corporate information and documents."

34. On this news, the Company's stock price fell from a closing price of $68.80 per share on November 12, 2021 to a closing price of $60.51 per share on November 15, 2021.

35. On November 17, 2021, the government agencies were revealed as the *Wall Street Journal* published an article reporting that the "Securities and Exchange Commission is investigating claims that Cassava Sciences Inc., the sixth-best performing U.S. stock this year, manipulated research results of its experimental Alzheimer's drug." Additionally, the National Institutes of Health ("NIH"), one of the world's foremost medical research centers which has awarded the Company $20 million in grants since 2015, also announced it was "examining the claims."

36. On that same day, another supplement was added to the Citizen's Petition, noting that the data "discrepancies" between the May 2020 Phase 2b study and the September 2020 Phase 2b study "***are so extreme that they suggest lab errors or manipulation***." (Emphasis added.) The supplement quoted the work of four scientists—Drs. Enea Milioris, Adrian Helibut, Jesse Brodkin, and Patrick Markey—all of whom believed that (1) Cassava and Dr. Wang had fabricated pre-clinical and clinical evidence for simufilam and (2) Dr. Wang's experiments "seem[ed] scientifically undoable."

37. On this news, the Company's stock price fell again, dropping from a closing price of $61.69 per share on November 16, 2021 to a closing price of $47.07 per share on November 17, 2021.

38. On December 9, 2021, a fourth and final supplement was added to the Citizen's Petition. The supplement revealed "irrefutable evidence of data manipulation/fabrication" in Cassava and Dr. Wang's 2017 *Neurobiology of Aging* paper—a foundational experiment used to demonstrate how simufilam treats Alzheimer's.

39. On this news, the Company's stock price again plummeted, from a closing price of $49.98 per share on December 8, 2021 to a closing price of $45.86 per share on December 9, 2021.

40. Subsequently, Dr. Bik conducted a review of the data in Dr. Wang's 2017 paper and noted her doubts that it was the "original data." On December 17, 2021, the *Journal of Neuroscience* published an Expression of Concern, wherein the publication sharply deviated from its original stance that a Cassava scientist had committed no wrongdoing in performing the Western blot research. Expressions of Concern are notices published at editors' discretion to alert readers of serious concerns about published work.[1] In relevant part, the Expression of Concern stated:

> The editors have been made aware of concerns about Western blots in this study, including those published with the article's erratum (Wang et al., 2021). These and other concerns are currently under investigation by the academic authorities at the [CUNY]. *JNeurosci* will await the outcome of that investigation before taking further action.

41. The *Journal of Neuroscience*'s Expression of Concern would be the first sign of doubt in a series of retractions that would follow Drs. Wang's and Burns' research.

42. Indeed, on February 4, 2022 the journal *Molecular Neurodegeneration* announced

[1]https://journals.plos.org/globalpublichealth/s/corrections-expressions-of-concern-and-retractions

it was retracting a paper it had published in 2021—which listed Dr. Wang as an author—because of irregularities found in data that had originated in Dr. Wang's laboratory. The paper's other authors requested the original blot data from Dr. Wang, but when he supplied the authors with the "original data," those images also had signs of manipulation. As a result, the paper was retracted.

43. Then, on March 22, 2022, the journal *Neurobiology of Aging* released an Expression of Concern for Drs. Burns and Wang's 2017 paper titled "PTI-125 binds and reverses an altered conformation of filamin A to reduce Alzheimer's disease pathogenesis." The Expression of Concern noted that, while there was no evidence of data manipulation, there were numerous data errors—many of which had been identified by the Citizens Petition.

44. Just eight days later, on March 30, 2022, the journal *PLOS One* retracted five of Drs. Wang's and Burns' papers. In all five of the retraction notices, the journal stated that "***the data and comments provided to PLOS did not resolve the concerns about the integrity and reliability of the reported data***." (Emphasis added.)

45. In the following months, public skepticism and negative press continued to plague Cassava. On April 18, 2022, *The New York Times* published an article interviewing nine "prominent experts for comment about the scientific underpinnings of Cassava's trials." Dr. Lawrence Honig, an Alzheimer's expert at Columbia University stated that "all the evidence" that supports simufilam "seems to be from [Dr. Wang's] lab." Likewise, Dr. Thomas Südhof, a Nobel laureate and neuroscientist at Stanford University, commented that the Company's "***overall conclusions with regard to Alzheimer's disease make no sense to me whatsoever***." (Emphasis added.)

46. On this news, the Company's stock price fell from a closing price of $22.46 per share on April 19, 2022 to a closing price of $20.39 per share on April 20, 2022.

47. The retractions of Dr. Wang's work continued. On June 1, 2022, the journal *Alzheimer's Research & Therapy* retracted Dr. Wang's paper published on July 27, 2017. The retraction notice stated:

> [C]oncerns have been raised regarding the [W]estern blot images presented in Figs. 1, 5, and 6. The authors have provided the raw data, which have been assessed by independent experts and ***deemed insufficient to address the concerns.*** The Editors-in-Chief ***therefore no longer have confidence in the integrity of the data in this article.***

(Emphasis added.)

48. Also on June 1, 2022, Drs. Helibut, Brodkin, Markey, and Milioris sent a joint email to editors and publishers of certain major journals, voicing their long standing concerns with Dr. Wang's research and publications. The email noted that Dr. Wang's "thirty-two papers dating back two decades" have raised research misconduct "***including data fabrication that has so far led to seven retractions, multiple Expressions of Concern, an investigation at CUNY, and at least three federal investigations***." (Emphasis added.) More poignantly, the email pointed out that all seven of Dr. Wang's papers that were retracted had been redacted ***after*** Dr. Wang "provided editors with supposedly 'original' images of 'uncropped blots.'" The email also noted that many of the journals that received this "original data" ultimately determined that it, too, had be cropped, and "observed clear evidence of fabrication."[2]

49. On this news, the Company's stock price fell from a closing price of $30.60 per share on May 31, 2022 to a closing price of $26.82 per share on June 1, 2022.

50. On July 27, 2022, the truth fully emerged when *Reuters* reported that the "U.S. Justice Department has opened a criminal investigation into [Cassava] involving whether the biotech company manipulated research results for [simufilam]."

[2] https://www.cassavafraud.com/docs/July2022_LetterToEditorsReWang_emailsRedacted.pdf

51. On this news, the Company's stock price fell from a closing price of $21.72 per share on July 26, 2022 to a closing price of $18.69 per share on July 27, 2022.

52. On May 11, 2023, this Court issued an order granting in part and denying in part Defendants' Motion to Dismiss in a consolidated federal securities fraud class action lawsuit brought in the United States District Court for the Western District of Texas captioned *In re Cassava Sciences, Inc. Securities Litigation,* Master File No. 1:21-CV-751-DAE (the "Securities Class Action") which alleged substantially similar false and misleading statements as those alleged herein. Notably, the only claims this Court dismissed were related to the deceased Dr. Nadav Friedmann based on a F.R.C.P. 25a. (ECF No. 104, at 32). On all other grounds, this Court denied the motion to dismiss, finding that plaintiffs in the Securities Class Action had stated with the requisite particularity and under heightened pleading standards facts giving rise to a strong inference of scienter and therefore cognizable claims upon which relief could be granted.

53. During the Relevant Period, the Individual Defendants breached their fiduciary duties by personally making and/or causing the Company to make to the investing public a series of materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements that failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the

Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

54. On October 12, 2023, the journal *Science* published an article entitled *Co-Developer of Cassava's Potential Alzheimer's Drug Cited for 'Egregious Misconduct.'* The article reported, among other things, that a City University of New York (CUNY) committee had accused Dr. Wang of scientific misconduct involving 20 research papers, many of which related to simufilam, and that Dr. Burns bears primary or partial responsibility for some of the misconduct.

55. The Individual Defendants also breached their fiduciary duties by causing the Company to submit to the FDA data that had been manipulated to make simufilam appear more effective than it was.

56. Moreover, the Individual Defendants breached their fiduciary duties by failing to correct and/or causing the Company to fail to correct these false and misleading statements and omissions of material fact. Additionally, in breach of their fiduciary duties, the Individual Defendants caused the Company to fail to maintain adequate internal controls.

57. In light of the Individual Defendants' misconduct—which has subjected the Company and certain of its directors and officers to being named as defendants in the Securities Class Action, and which has further subjected the Company to the need to undertake internal

investigations, the need to implement adequate internal controls, losses from the waste of corporate assets, and losses due to the unjust enrichment of Individual Defendants who were improperly overcompensated by the Company and/or who benefitted from the wrongdoing alleged herein—the Company will have to expend many millions of dollars. Additionally, the Individual Defendants face substantial likelihood of liability as a result of the Securities Class Action surviving in part Defendants' Motion to Dismiss.[3]

58. The Company has been substantially damaged as a result of the Individual Defendants' knowing or highly reckless breaches of fiduciary duty and other misconduct.

59. In light of the breaches of fiduciary duty engaged in by the Individual Defendants, most of whom are the Company's current directors, of the collective engagement in fraud and misconduct by the Company's directors, of the substantial likelihood of the directors' liability in this derivative action and of certain directors' and officers' liability in the Securities Class Action, and of their not being disinterested and/or independent directors, a majority of the Company's Board cannot consider a demand to commence litigation against themselves on behalf of the Company with the requisite level of disinterestedness and independence.

JURISDICTION AND VENUE

60. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise a federal question under Section 14(a) of the Exchange Act (15 U.S.C. § 78n(a)(1)), Rule 14a-9 of the Exchange Act (17 C.F.R. § 240.14a-9), Section 10(b) of the Exchange Act (15. U.S.C. § 78j(b)), and Section 21D of the Exchange Act (15 U.S.C. § 78u-4(f)).

[3] All of the Securities Class Action plaintiffs' claims survived the motion to dismiss, except the claims against the deceased Nadav Friedmann.

Plaintiff' claims also raise a federal question pertaining to the claims made in the Securities Class Action based on violations of the Exchange Act.

61. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367(a).

62. This derivative action is not a collusive action to confer jurisdiction on a court of the United States that it would not otherwise have.

63. Venue is proper in this District because the alleged misstatements and wrongs complained of herein entered this District, the Defendants have conducted business in this District, and Defendants' actions have had an effect in this District. In addition, the Company's principal executive offices are located in this District.

PARTIES

Plaintiff Stephen Kearney

64. Plaintiff is a current shareholder of Cassava. Plaintiff has continuously held Cassava common stock at all relevant times.

Nominal Defendant Cassava

65. Cassava is a Delaware corporation with its principal executive offices at 7801 N. Capital of Texas Highway, Suite 260, Austin, Texas 78731. Cassava's shares trade on the NASDAQ Capital Market ("NASDAQ") under the ticker symbol "SAVA."

Defendant Barbier

66. Defendant Remi Barbier ("Barbier") is the Company's President, CEO, and Chairman of the Board and has served in all three roles since he founded the Company in May 1998. Defendant Barbier has been married to Defendant Lindsay Burns, the self-described "project leader" since at least 2006. According to the Company's Schedule 14A filed with the SEC on March 27, 2023 (the "2023 Proxy Statement"), as of March 16, 2023, Defendant Barbier

beneficially owned 2,031,594 shares of the Company's common stock, representing 4.8% of the Company's outstanding common stock. Given that the price per share of the Company's common stock at the closing of trade on March 16, 2023 was $26.75, Defendant Barbier owned approximately $54 million worth of Cassava stock.

67. For the fiscal year ended December 31, 2022 (the "2022 Fiscal Year"), Defendant Barbier received $1,114,998 in total compensation from the Company, including $1,100,000 in salary and $14,998 in all other compensation. For the fiscal year ended December 31, 2021 (the "2021 Fiscal Year"), Defendant Barbier received $1,741,120 in total compensation from the Company, including $975,000 in salary, $750,000 in bonus, and $16,120 in all other compensation. For the fiscal year ended December 31, 2020 (the "2020 Fiscal Year"), Defendant Barbier received $936,120 in total compensation from the Company, including $920,000 in salary and $16,120 in all other compensation.

68. The 2023 Proxy Statement stated the following about Defendant Barbier:

> *Remi Barbier*, the Company's founder, has served as President, Chief Executive Officer and Chairman of the Board of Directors since the Company's inception in 1998. Prior to that time, Mr. Barbier helped in the growth or founding of Exelixis Inc., a publicly-traded drug development company, ArQule, Inc., a drug development company acquired by Merck & Co., and EnzyMed, Inc., a chemistry company acquired by Albany Molecular Research, Inc. Mr. Barbier is a trustee emeritus of the Carnegie Institute of Washington, the Santa Fe Institute, the Advisory Board of the University of California Institute for Quantitative Biosciences and a life science incubator at the University of Arkansas for Medical Sciences. Mr. Barbier received his B.A. from Oberlin College and his M.B.A. from the University of Chicago.

Defendant Burns

69. Defendant Lindsay Burns ("Burns") has served as the Company's Senior Vice President, Neuroscience since January 2002. Defendants Burns has been married to Defendant Barbier since at least 2006.

70. The Company's website states the following about Defendant Burns:

> **Sr. VP, Neuroscience**
>
> Lindsay H. Burns, PhD has been the lead scientist on Cassava Sciences' Alzheimer's disease program since she and Dr. Hoau-Yan Wang discovered simufilam's novel target. Dr. Burns has led the program through medicinal chemistry, lead profiling and IND-enabling studies to its current stage of clinical trials in Alzheimer's disease patients. Trained in neuropsychology at the University of Cambridge and Harvard College, Dr. Burns has a broad background in neuroscience and neurodegenerative disease that spans functional in vitro assays, preclinical models of disease and cognitive/behavioral testing.

Defendant Schoen

71. Defendant Eric J. Schoen ("Schoen") has served as the Company's Chief Financial Officer ("CFO") since October 2018. According to the 2023 Proxy Statement, as of March 16, 2023, Defendant Schoen beneficially owned approximately 71,800 shares of the Company's common stock. Given that the price per share of the Company's common stock at the closing of trade on March 16, 2023 was $26.75, Defendant Schoen owned approximately $1.9 million worth of Cassava stock.

72. For the 2022 Fiscal Year, Defendant Schoen received $426,610 in total compensation from the Company, including $425,000 in salary and $1,610 in all other compensation. Effective January 1, 2022, the Company announced that Defendant Schoen's salary was increased by 55% between the 2021 Fiscal Year and 2022 Fiscal Year.

73. For the 2021 Fiscal Year, Defendant Schoen received $776,932 in total compensation from the Company, including $275,000 in salary, $500,000 in bonus compensation, and $1,369 in all other compensation.

74. For the 2020 Fiscal Year, Defendant Schoen received $251,932 in total compensation from the Company, including $250,000 in salary and $1,932 in all other compensation.

75. The 2022 Proxy Statement stated the following about Defendant Schoen:

> *Eric Schoen* has served as Chief Financial Officer since October 2018. Prior to joining the Company, Mr. Schoen served in numerous financial leadership roles. Most recently, he served as Vice President, Senior Vice President, Finance and Chief Accounting Officer of Aspira Women's Health Inc. (formerly Vermillion, Inc.), a publicly-held women's health company, from 2011 to 2017. Mr. Schoen also began his career and spent nine years with PricewaterhouseCoopers in the audit and assurance, transaction services and global capital markets practices. Mr. Schoen received his B.S. in Finance from Santa Clara University.

Defendant Kupiec

76. Defendant James W. Kupiec ("Kupiec") served as the Company's Chief Clinical Development Officer ("CCDO") from January 4, 2021, until his promotion to Chief Medical Officer on December 19, 2022.

77. For the 2022 Fiscal Year, Defendant Kupiec received $400,000 in total compensation from the Company, the entirety of which was given as salary.

78. For the 2021 Fiscal Year, Defendant Kupiec received $473,579 in total compensation from the Company, including $373,579 in salary and $100,000 in bonus compensation.

79. The 2022 Proxy Statement stated the following about Defendant Kupiec:

> *James W. Kupiec, M.D.* has served as our Chief Medical Officer since December 2022 and previously served as our Chief Clinical Development Officer from January 2021 to December 2022. Dr. Kupiec joined the Company after three decades of drug development experience at Pfizer, Sanofi and Ciba-Geigy. Dr. Kupiec previously served as Vice President, Global Clinical Leader for Parkinson's Disease and Clinical Head of the Neuroscience Research Unit for Pfizer, Inc., in Cambridge, MA. He joined Pfizer in 2000 after seven years with Sanofi, and two years with Ciba-Geigy Pharmaceuticals. During his 17-year career at Pfizer, Dr. Kupiec had extensive governance, business development, alliance and leadership responsibilities. Dr. Kupiec earned his BS with Honors in Biochemistry at Stony Brook University and his MD from the Albert Einstein College of Medicine. He completed his residency training at the Strong Memorial Hospital, University of Rochester School of Medicine, and is certified by the American Board of Internal Medicine. He served as an investigator on many clinical trials before joining the pharmaceutical industry.

Defendant Marsman

80. Defendant Michael Marsman ("Marsman") serves as a consultant to the Company and prior to that as Senior Vice President of Regulatory Affairs for the Company since April 2015. The Company's website states that Defendant Marsman has "worked with SAVA as an employee or consultant since 2004."

81. The April 23, 2015 press release that announced Defendant Marsman was joining the Company, then-known as Pain Therapeutics, Inc., stated the following:

> Pain Therapeutics, Inc. (Nasdaq:PTIE), a clinical-stage biopharmaceutical company, announced the appointment of Michael Marsman, Pharm.D., as Senior Vice President, Regulatory Affairs. Dr. Marsman will be responsible for developing and implementing regulatory strategies to gain drug approvals. He previously led regulatory affairs at Pain Therapeutics for nearly a decade before leaving in 2012 amid a corporate reorganization.
>
> "We're honored Dr. Marsman has decided to rejoin our management team," said Remi Barbier, Chairman, President & CEO. "I believe his appointment is testament to our potential for growth."
>
> "I'm excited by what I see here at Pain Therapeutics," said Dr. Marsman, SVP, Regulatory Affairs. . ..
>
> Dr. Marsman most recently served as V.P. Regulatory Affairs at Impax Laboratories (Nasdaq:IPXL). Before that, he led Regulatory Affairs at Pain Therapeutics for nearly ten years. Before that he also held senior positions at Millennium Pharmaceuticals, COR Therapeutics, Sequus Pharmaceuticals and Syntex, where he had shared responsibility for the regulatory approval of several high-profile drugs.

Defendant Barry

82. Defendant Rick J. Barry ("Barry") has served as a Company director since June 11, 2021. He also serves as chair of the Nominating & Governance Committee and the Audit Committee. According to the 2023 Proxy Statement, as of March 16, 2023, Defendant Barry beneficially owned 275,000 shares of the Company's common stock. Given that the price per share

of the Company's common stock at the closing of trade on March 16, 2023 was $26.75, Defendant Barry owned approximately $7.3 million worth of Cassava stock.

83. The 2022 Proxy Statement stated the following about Defendant Barry:

> Richard J. Barry has served as a director since June 2021. Since June 2015, Mr. Barry has also served as a director of Sarepta Therapeutics, Inc., (Nasdaq: SRPT). Mr. Barry has extensive experience in the investment management business. He was a founding member of Eastbourne Capital Management LLC, and served as a Managing General Partner and Portfolio Manager from 1999 to its close in 2010. Prior to Eastbourne, Mr. Barry was a Portfolio Manager and Managing Director of Robertson Stephens Investment Management. Mr. Barry holds a Bachelor of Arts from Pennsylvania State University.

Defendant Gussin

84. Defendant Robert Z. Gussin ("Gussin") has served as a Company director since March 2003. He also serves as a member of both the Audit Committee and Compensation Committee. According to the 2023 Proxy Statement, as of March 16, 2023, Defendant Gussin beneficially owned 142,537 shares of the Company's common stock. Given that the price per share of the Company's common stock at the closing of trade on March 16, 2023 was $26.75, Defendant Gussin owned approximately $3.8 million worth of Cassava stock as of that date.

85. For the 2020 Fiscal Year, Defendant Gussin received $75,924 in compensation from the Company, all in option awards.

86. The 2022 Proxy Statement stated the following about Defendant Gussin:

> *Robert Z. Gussin, Ph.D.* has served as a director since March 2003. Dr. Gussin worked at Johnson & Johnson for 26 years, most recently as Chief Scientific Officer and Corporate Vice President, Science and Technology from 1986 through his retirement in 2000. Dr. Gussin served on the board of directors of Duquesne University and the advisory boards of the Duquesne University Pharmacy School and the University of Michigan Medical School Department of Pharmacology. Dr. Gussin received his B.S. and M.S. degrees and D.Sc. with honors from Duquesne University and his Ph.D. in Pharmacology from the University of Michigan, Ann Arbor.

Defendant O'Donnell

87. Defendant Michael J. O'Donnell ("O'Donnell") has served as a Company director since June 1998. According to the 2023 Proxy Statement, as of March 16, 2023, Defendant O'Donnell beneficially owned 89,666 shares of Company common stock. Given that the price per share of the Company's common stock at the closing of trade on March 16, 2023 was $26.75, Defendant O'Donnell owned approximately $2.3 million worth of Cassava common stock.

88. For the 2022 Fiscal Year, Defendant O'Donnell did not receive compensation for his role as a director. However, the Company paid the law firm Orrick, Herrington & Sutcliffe LLP, where Defendant O'Donnell is a partner, $3.7 million in legal fees.

89. For the 2021 Fiscal Year, Defendant O'Donnell did not receive compensation for his role as a director. However, the Company paid the two law firms[4] where Defendant O'Donnell was a partner during 2021 a collective $942,000 for legal services.

90. The 2022 Proxy Statement stated the following about Defendant O'Donnell:

> *Michael J. O'Donnell, Esq*. has served as a director since 1998. Mr. O'Donnell has been a partner in the law firm of Orrick, Herrington & Sutcliffe LLP since June 2021. Orrick, Herrington & Sutcliffe LLP is the Company's corporate counsel and provides legal services to the Company. Previously, Mr. O'Donnell was a member of Morrison & Foerster LLP from 2011 to 2021. Mr. O'Donnell serves as corporate counsel to numerous public and private biopharmaceutical and life sciences companies. Previously, Mr. O'Donnell was a member of Wilson Sonsini Goodrich & Rosati. Mr. O'Donnell received his J.D., cum laude, from Harvard University and his B.A. from Bucknell University, summa cum laude.

Defendant Robertson

91. Defendant Sanford R. Robertson ("Robertson") has served as a Company director since September 1998. He serves as a member on each of the Audit Committee, the Compensation Committee, and the Nominating and Governance Committee. In addition, he serves as Lead

[4] Defendant O'Donnell was partner at Morrison & Foerster LLP until June 2021, at which point he became a partner at Orrick, Herrington & Sutcliffe LLP.

Director. According to the 2023 Proxy Statement, as of March 16, 2023, Defendant Robertson beneficially owned 1,161,694 shares of Company common stock, representing 2.8% of all outstanding shares. Given that the price per share of the Company's common stock at the closing of trade on March 16, 2023 was $26.75, Defendant Robertson owned approximately $4.3 million worth of Cassava common stock.

92. For the 2020 Fiscal Year, Defendant Robertson received $75,924 in compensation from the Company, all in options awards.

93. The 2022 Proxy Statement stated the following about Defendant Robertson:

> *Sanford R. Robertson* has served as a director since September 1998. Mr. Robertson has been a partner of Francisco Partners, a technology buyout fund, since 1999. Prior to founding Francisco Partners, Mr. Robertson was the founder and chairman of Robertson, Stephens & Company, a technology investment bank sold to BankBoston in 1998. Mr. Robertson is the lead director of Salesforce.com, a publicly-held provider of enterprise cloud computing applications. Mr. Robertson received his B.A. and M.B.A. degrees with distinction from the University of Michigan.

Defendant Scannon

94. Defendant Patrick J. Scannon ("Scannon") has served as a Company director since December 2007. During the Relevant Period, he served on the Audit Committee. According to the 2023 Proxy Statement, as of March 16, 2023, Defendant Scannon beneficially owned 92,955 shares of Company common stock. Given that the price per share of the Company's common stock at the closing of trade on March 16, 2023 was $26.75, Defendant Scannon owned approximately $2.48 million worth of Cassava common stock.

95. For the 2020 Fiscal Year, Defendant Scannon received $37,962 in compensation from the Company, all in option awards.

96. The 2022 Proxy Statement stated the following about Defendant Scannon:

> *Patrick J. Scannon, M.D., Ph.D.* has served as a director since December 2007. Dr. Scannon is one of the founders of XOMA. From 2006 to 2016, Dr. Scannon was

Executive Vice President, Chief Biotechnology Officer of XOMA. From 1993 to 2006, Dr. Scannon served as Chief Scientific and Medical Officer of XOMA. Dr. Scannon retired from XOMA and resigned from XOMA's board of directors in 2016. Dr. Scannon received his Ph.D. in organic chemistry from the University of California, Berkeley and his M.D. from the Medical College of Georgia.

RELEVANT NON-PARTIES

Dr. Nadav Friedmann

97. Dr. Nadav Friedmann[5] ("Dr. Friedmann") served as a director of the Company from September 1998 to 2022 and as the Company's Chief Medical Officer from 2001 to 2022. On December 20, 2022, Dr. Friedmann passed away.

Dr. Hoau-Yan Wang

98. Dr. Hoau-Yan Wang ("Dr. Wang") is a medical professor at CUNY Medical School. Dr. Wang serves as a member of the Company's scientific advisory board and is described on the Company's website as the "co-lead scientist on discovery & development of simufilam and SavaDx." Dr. Wang was included in the Plan and entitled to bonuses based on Cassava's stock price.

FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS

99. By reason of their positions as officers, directors, and/or fiduciaries of Cassava and because of their ability to control the business and corporate affairs of Cassava, the Individual Defendants owed Cassava and its shareholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage Cassava in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Cassava and its shareholders so as to benefit all shareholders equally.

[5] Dr. Friedmann was originally a defendant in the Securities Class Action. However, all claims against him were dismissed in a motion to dismiss following his passing in December 2022. ECF No. 130, at 32.

100. Each director and officer of the Company owes to Cassava and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company and in the use and preservation of its property and assets and the highest obligations of fair dealing.

101. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Cassava, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

102. To discharge their duties, the officers and directors of Cassava were required to exercise reasonable and prudent supervision over the management, policies, controls, and operations of the Company.

103. Each Individual Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the highest fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Cassava, the absence of good faith on their part, or a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company. The conduct of the Individual Defendants who were also the officers and directors of the Company has been ratified by the remaining Individual Defendants who collectively comprised a majority of Cassava's Board at all relevant times.

104. As the senior executive officers and/or directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, the Individual Defendants had a duty to prevent and not to effect the dissemination of

inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, operations, financial statements, business, products, management, earnings, internal controls, and present and future business prospects, including the dissemination of false information regarding the Company's business, prospects, and operations, and had a duty to cause the Company to disclose in its regulatory filings with the SEC all those facts described in this Complaint that it failed to disclose, so that the market price of the Company's common stock would be based upon truthful and accurate information. Further, they had a duty to ensure the Company remained in compliance with all applicable laws.

105. To discharge their duties, the officers and directors of Cassava were required to exercise reasonable and prudent supervision over the management, policies, practices, and internal controls of the Company. By virtue of such duties, the officers and directors of Cassava were required to, among other things:

(a) ensure that the Company was operated in a diligent, honest, and prudent manner in accordance with the laws and regulations of Delaware, Texas, and the United States, and pursuant to Cassava's own Code of Ethics;

(b) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) remain informed as to how Cassava conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;

(d) establish and maintain systematic and accurate records and reports of the business and internal affairs of Cassava and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;

(e) maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Cassava's operations would comply with all applicable laws and Cassava's financial statements and regulatory filings filed with the SEC and disseminated to the public and the Company's shareholders would be accurate;

(f) exercise reasonable control and supervision over the public statements made by the Company's officers and employees and any other reports or information that the Company was required by law to disseminate;

(g) refrain from unduly benefiting themselves and other Company insiders at the expense of the Company; and

(h) examine and evaluate any reports of examinations, audits, or other financial information concerning the financial affairs of the Company and to make full and accurate disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above.

106. Each of the Individual Defendants further owed to Cassava and the shareholders the duty of loyalty requiring that each favor Cassava's interest and that of its shareholders over their own while conducting the affairs of the Company and refrain from using their position, influence, or knowledge of the affairs of the Company to gain personal advantage.

107. At all times relevant hereto, the Individual Defendants were the agents of each other and of Cassava and were at all times acting within the course and scope of such agency.

108. Because of their advisory, executive, managerial, directorial, and controlling positions with Cassava, each of the Individual Defendants had access to adverse, nonpublic information about the Company.

109. The Individual Defendants, because of their positions of control and authority, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Cassava.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

110. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their wrongdoing. The Individual Defendants caused the Company to conceal the true facts as alleged herein. The Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

111. The purpose and effect of the conspiracy, common enterprise, and/or common course of conduct was, among other things, to: (i) facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, waste of corporate assets, gross mismanagement, abuse of control, and violations of the Exchange Act; (ii) conceal adverse information concerning the Company's operations, financial condition, legal compliance, future business prospects, and internal controls; and (iii) artificially inflate the Company's stock price.

112. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company purposefully or recklessly to conceal material facts, fail to correct such misrepresentations, and violate applicable laws. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein. Because the actions described herein occurred under

the authority of the Board, each of the Individual Defendants who is a director of Cassava was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

113. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each of the Individual Defendants acted with actual or constructive knowledge of the primary wrongdoing, either took direct part in, or substantially assisted in the accomplishment of that wrongdoing, and was or should have been aware of his overall contribution to and furtherance of the wrongdoing.

114. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of Cassava, and each was at all times acting within the course and scope of such agency.

CASSAVA'S CODE OF ETHICS AND CORPORATE GOVERNANCE

Cassava's Code of Ethics

115. Cassava's Code of Ethics states that its purpose is to:

- Promote honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;

- Promote full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with, or submits to the U.S. Securities and Exchange Commission and in other public communications made by the Company;

- Promote compliance with applicable governmental laws, rules and regulations;

- Promote the prompt internal reporting of violations of the Code to appropriate persons of authority within the Company; and

- Promote accountability for adherence to the Code.

116. Moreover, the Company's Code of Ethics states:

All directors, officers and employees of the Company will:

> 1. Act with honesty and integrity, avoiding actual or apparent conflicts between personal and the interests of the Company, including refraining from receiving improper personal benefits as a result of holding a particular position with the Company;
>
> * * *
>
> 3. Where applicable, provide the U.S. Securities and Exchange Commission (the "Commission") and the public with complete, fair, accurate, timely and understandable disclosure in periodic reports and other documents filed or submitted to the Commission and in other public communications;
>
> 4. Endeavor to comply with applicable laws and regulations of federal, state, local and foreign governments and government agencies having jurisdiction over the Company, and with applicable regulations of private or self-regulatory authorities having jurisdiction over the Company;
>
> 5. Act in good faith, responsibly with due care and diligence and without misrepresentation or omission of material facts and strive to maintain independent judgment in the performance and fulfillment of their duties and responsibilities;
>
> 6. Promote ethical behavior among subordinates and peers at the Company[.]

117. Finally, with regard to reporting violations of the Code of Ethics itself, the Code of Ethics further provides that: "It is the duty of each director, officer and employee of the Company to report violations of the Code promptly to the attention of the Company's Chief Executive Officer, Chief Financial Officer or to any member of the Audit Committee of the Board[.]"

Audit Committee Charter

118. The Company's Audit Committee Charter states that one of the Audit Committee's purposes "shall be to make such examinations as are necessary to monitor the Company's system of internal controls [and] to provide the Company's Board of Directors with the results of its examinations and recommendations derived therefrom[.]"

119. The Audit Committee Charter also describes the Audit Committee's responsibilities which include "[r]eviewing on a continuing basis the adequacy of the Company's

system of internal controls" and "[r]eviewing, in conjunction with counsel, any legal matters that could have a significant impact on the Company's financial statements[.]"

120. The Individual Defendants violated the Code of Ethics by engaging in or permitting the scheme to submit manipulated data to the FDA and to issue materially false and misleading statements to the public, including in the Company's SEC filings; by facilitating and disguising the Individual Defendants' violations of law, including breaches of fiduciary duty, waste of corporate assets, unjust enrichment, abuse of control, gross mismanagement, and violations of the Exchange Act; and by failing to report the same. Moreover, the Individual Defendants violated the Code of Ethics by failing to act with honesty and integrity; failing to provide the SEC and public with complete, fair, accurate, timely, and understandable disclosures; failing to comply with applicable laws and regulations; failing to act in good faith, responsibly with due care and diligence and without misrepresentation or omission of material facts; failing to promote ethical behavior at the Company; and failing to promptly report violations of the Code of Ethics. Further in violation of the Audit Committee Charter, Defendants Barry, Gussin, Robertson, and Scannon failed to adequately review the Company's internal controls as well as the Company's SEC filings and FDA submissions.

THE INDIVIDUAL DEFENDANTS' MISCONDUCT

Relevant Background on the Company's Business

121. Cassava is a biotechnology company founded in 2002 under the name Pain Therapeutics. The Company has a product portfolio including simufilam, its lead therapeutic product candidate, and SavaDx, its lead investigational diagnostic product candidate. Simufilam is an Alzheimer's treatment, and SavaDx is a test to detect the presence of Alzheimer's before the appearance of clinical symptoms.

122. Prior to investing in the development of simufilam, the Company's central focus and investment had been the development of Remoxy. Cassava began developing Remoxy in 2002. Remoxy was a gel form of the opioid oxycodone, created for the purpose of deterring drug abuse. Unfortunately for Cassava, Remoxy faced hurdles from the FDA. In 2008, the Company filed its first New Drug Application ("NDA") with the FDA, and was subsequently rejected.[6] In June 2011, the Company tried a second time to get Remoxy approved, only to once again get rejected.[7] Then, in 2016, the Company was reprimanded by the FDA for marketing violations by overstating the benefits of the unapproved Remoxy.[8] After four attempts at FDA approval, the Company received its final rejection and a Complete Response Letter from the FDA, officially denying the Company's Remoxy NDA. The FDA asserted that "[t]he data submitted in [the] NDA do not support the conclusion that the benefits of [Remoxy] Extended-Release Capsules outweigh the risks."[9]

123. Defendant Barbier lashed out against the FDA's decision, calling the denial "an ideological judgment call that is vague in nature but conclusive in its damaging effects."

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[6] Amirah Al Idrus, "FDA Panel Rejects Pain Therapeutics' Abuse-Deterrent Opioid Remoxy", FIERCE BIOTECH (Jun. 26, 2018), https://www.fiercebiotech.com/fda-panel-rejects-pain-therapeutics-abuse-deterrent-opioid-remoxy#:~:text=FDA%20panel%20rejects%20Pain%20Therapeutics'%20abuse%2Ddeterrent%20opioid%20Remoxy,-By%20Amirah%20Al&text=Pain%20Therapeutics%20can't%20seem,from%20Durect%20back%20in%202002

[7] *Id.*

[8] Koung Lee and Samuel M. Skariah, "RE: NDA 022324 Remoxy (oxycodone) Extended-Release Capsules M5", DEP'T. HEALTH & HUM. SERV. https://pink.pharmaintelligence.informa.com/-/media/supporting-documents/pink-sheet/2016/11/opdp-letter-on-remoxy-er-websites-09-08-2016.pdf

[9] Da Hee Han, "FDA Issues Complete Response Letter Rejecting Remoxy Approval", MEDICAL PROFESSIONALS REFERENCE (Aug. 6, 2018), https://www.empr.com/home/news/drugs-in-the-pipeline/fda-issues-complete-response-letter-rejecting-remoxy-approval/.

124. The regulatory failures of the Company's premiere drug erased most of its stock value, dropping to below a $1 by the closing of trade on August 17, 2018. While Remoxy's failure had erased shareholder value, Defendant Barbier had found two decades of FDA rejections to be profitable, securing just under $27 million in compensation by the end of fiscal year 2018.[10]

The Company Rebrands and Shifts Focus to Simufilam

125. Following the failures of Remoxy, the Company rebranded to its current name, Cassava Sciences, Inc., and announced a strategic reorganization. The Company was shifting its focus to the development of an Alzheimer's disease medication named simufilam. In the Company's annual report published on Form 10-K on March 29, 2019, the Company acknowledged it had a "limited operating history… targeting Alzheimer's disease and no history of product approvals for commercial sale[.]" In a press release published on March 27, 2019, the Company emphasized the development of PTI-125 (which would later be called simufilam) was based on "science… published in several prestigious, peer-reviewed technical journals, including *Journal of Neuroscience, Neurobiology of Aging, and Journal of Biological Chemistry*."

126. In SEC filings, the Company reports that simufilam SavaDx were "discovered" and designed in-house" between 2008 to 2018. The Company reported that early experimental trials were successful for simufilam, resulting in two research grants for $6.7 million from the National Institute of Health ("NIH").

127. Simufilam represents a potent opportunity for a pharmaceutical company that runs at a loss each year and has yet to secure FDA approval for any drug. The Alzheimer's Association

[10] Adam Feuerstein, "Failure has Paid Handsomely for Cassava Sciences' CEO. His Latest Cash Grab is a Risky Alzheimer's Drug", STAT NEWS (Oct. 2, 2020), https://www.statnews.com/2020/10/02/failure-has-paid-handsomely-for-cassava-sciences-ceo-his-latest-cash-grab-is-a-risky-alzheimers-drug/.

estimates that nearly 6.7 million Americans suffer from Alzheimer's disease—a number that could rise to 12.7 million by 2050. As such, Analyst Jason McCarthy of Maxim Group estimates that the success simufilam could likely result in a hefty 180% increase on the Company's stock price. Meanwhile, analyst Larry Ramer of Yahoo! Finance predicts that simufilam's success could generate as much as $150 billion annually in profit for the Company.

128. One of the Company's larger competitors, Biogen Inc. ("Biogen"), recently received FDA approval for its Alzheimer's treatment, Aduhelm. However, simufilam represents an appealing potential alternative to Aduhelm, if it were to receive FDA approval, given that it is taken orally, rather than intravenously, and that it is expected to be much cheaper, with Aduhelm costing approximately $56,000 per patient per year.

129. Cassava is under great pressure to get one or both of its lead product candidates to market, given that, according to the Company's most recent Form 10-Q filed with the SEC on May 1, 2023, Cassava "ha[s] yet to generate any revenues from product sales" and "ha[s] an accumulated deficit of $307.8 million at March 31, 2023." In the poignant words of Defendant Barbier, "[Cassava] is a moonshot with one rocket ship." As such, the death of simufilam would mean the death of the Company.

130. Simufilam is a unique Alzheimer's medication as it seeks to not only treat the symptoms of Alzheimer's disease, but also to reverse the disease. Simufilam targets filamin A (FLNA), a protein that Cassava's scientists say is often misshaped in the brains of Alzheimer's patients. As the Company explains, altered FLNA results in "neuronal dysfunction, neuronal degeneration, and neuroinflammation." As such, repairing FLNA is believed to result in improved brain health aimed at treating neurodegeneration.

The Shaky Science of Simufilam

131. While the Company has touted simufilam as being supported by a "strong scientific rationale" and by it being "published in multiple peer-reviewed journals," fellow scientists have called into question the Company's methods. For one, the foundational science the Company uses to support its claims of simufilam's effectiveness is based on a series of papers from two coauthors, Dr. Hoau-Yan Wang of City University of New York and Dr. Lindsay Burns of Cassava. Both have long-standing financial and personal relationships with Cassava. According to the Citizen's Petition, no other labs have been able to confirm Cassava's findings regarding simufilam. Similarly, while the Company has touted the success of its trials, the Citizen's Petition and other experts have discovered clear signs of data manipulation present in a number of Drs. Wang's and Burns' publications. In some instances, the publishing journals would go on to issue retractions.

132. Drs. Wang and Burns purportedly began development of simufilam with "basic research around the neurobiology of Filamin A" in 2008. In 2008, the pair published a paper titled "High-Affinity Naloxone Binding to Filamin A Prevents Mu Opioid Receptor-Gs Coupling Underlying Opioid Tolerance and Dependence" in *PLOS One*. This paper—which would later be retracted by the journal—presented data that "the opioid receptor antagonists naloxone and naltrexone bind a specific site on FLAN with high affinity." This conclusion led to Dr. Wang's later purported discovery that FLNA-binding compounds could be targeted to restore the protein to its normal shape, ultimately leading to the development of simufilam.

133. Drs. Wang and Burns next began testing in animal models, which allegedly "resulted in dramatic improvements in brain health, such as reduced amyloid and tau deposits, improved receptor signaling and improved learning and memory." Drs. Wang and Burns were able

to continue publishing their discoveries on simufilam in peer-reviewed journals allowing the Company to assert that "key publications" had validated the Company's scientific approach.

134. The Company leveraged these pre-clinical studies with the NIH and obtained $20 million in grants over the years. Additionally, these pre-clinical studies afforded Cassava the opportunity to open an Investigational New Drug ("IND") application in 2017. Accordingly, the Company began Phase 2 studies in September 2019.

Cassava's Phase 2b Trial Reanalysis

135. Cassava began its Phase 2b trials in September 2019. It began with a Phase 2b study, which was a place-controlled, blinded trial, that was to assess simufilam's efficacy at treating Alzheimer's.

136. The NIH-funded study randomized 64 patients to receive either simufilam or a placebo for a 28-day period. The goal was to measure the primary endpoint of biomarkers in Alzheimer's disease patients, determining whether necessary baselines had improved over the 28-day period. Additionally, the study assessed the patients' cognitive faculties.

137. On May 15, 2020, the Company announced in a press release that "[Cassava] today reported top-line results from a Phase 2b study of PTI-125, its lead investigational drug in patients with Alzheimer's disease. This study did not meet its primary endpoint."

138. The disappointing results of the Phase 2b study put the Company's future into question. The press release resulted in a sharp decline of the Company's stock and left analysts questioning what path forward the Company could have.

139. However, in the May 15 press release, Defendant Barbier provided pointed comments that the test was "conducted by outside labs" they had "never worked with" before. Defendant Barbier noted that the "results disappoint and are not consistent with previous clinical

experience for reasons that are unclear at the moment." Defendant Barbier assured investors that the Company planned to "re-analyze CSF biomarkers from study participants."

140. In an August 12, 2020 press release, the Company again noted that it had "no prior work experience" with the lab who performed the May analysis of the Phase 2b study. Further, the Company described the disappointing results as "anomalous and highly improbable." As such, the Company had Dr. Wang's lab—which they represented to the public as a new "outside lab"—to re-analyze the results, which it planned to announce in September 2020.

141. On September 14, 2020, the Company announced in a press release the results of its re-analysis of the Phase 2b data. The Company assured investors that "[a]ll CSF samples were sent to outside labs for bioanalysis." The re-analysis revealed that, actually "simufilam significantly improved an entire panel of validated biomarkers of disease in patients with Alzheimer's disease." The Company asserted that the May 15 results of the Phase 2b study "serve[] no useful purpose."

142. The Company, however, failed to provide clear evidence that the initial lab had improperly conducted the analysis. In fact, emails produced by the NIH from a Freedom of Information Act request revealed the initial results were produced by Lund University, a world-renowned public research university in Sweden. Defendant Barbier asserted in a presentation to investors on September 14, 2020, that "Clearly, mistakes were made on their behalf…. It's hard for anyone to fess up exactly what happened and when and who did what." Similarly, the Company's presentation emphasized that "[a]n academic lab conducted" the re-analysis. What the Company failed to disclose, however, is that this "academic lab" was Dr. Wang's lab.

143. The market received the Company's new results well, as the Company's stock price climbed over the weekend from a closing price of $3.32 on September 11, 2020 to a closing price of $7.75 on September 14, 2020.

The Plan

144. On September 1, 2020, the Company announced on a Form 8-K filed with the SEC that the Board had approved the Plan for its executives on August 26, 2020. This was just a bit more than two weeks prior to the Company's unveiling of the re-analysis of the Phase 2b results on September 14, 2020. Meanwhile, Dr. Wang had been providing Dr. Burns with the biomarker data for the re-analysis as early as June 12, 2020.

145. As such, the Defendants were aware of the positive results of the re-analysis prior to the approval of the Plan.

146. The Plan afforded bonuses if the Company's market capitalization exceeded $200 million for 20 consecutive business days. In total, the Plan set aside a cash bonus pool of $10 million. The Board was entitled to split the $10 million pursuant to the publicly announced Plan. The Plan laid out that Defendant Barbier was entitled to "at least 33.3% of the aggregate bonus payment," while Dr. Friedmann and Defendant Schoen were portioned at "33.3% and 23.3%, respectively." The remainder of the Board members were entitled to "2% of the aggregate bonus payment set out in the Plan… subject to a reasonable increase for members of committees of the Board."

147. Sure enough, the newly announced Phase 2b results propelled the Company to meet its $200 million market capitalization goal for 20 consecutive days. On October 13, 2020, the Company announced it had "achieved the first Valuation milestone" and "approved a cash bonus award of $7.3 million in total for all Plan participants."

148. The Plan afforded the Board even more opportunity to obtain bonuses. The Company's Form 10-Q filed with the SEC on August 4, 2021 for the quarter ended June 30, 2021, stated:

> If the Company were to exceed a $5 billion market capitalization for no less than 20 consecutive trading days, all Valuation Milestones would be deemed achieved, in which case cash bonus awards would range ***from a minimum of $139.1 million up to a hypothetical maximum of $322.3 million***. Payment of cash bonuses is deferred until such time as (1) the Company completes a Merger Transaction, or (2) the Compensation Committee determines the Company has sufficient cash on hand to render payment (each, a "Performance Condition"), neither of which may ever occur. Accordingly, there can be no assurance that Plan participants will ever be paid a cash bonus that is awarded under the Plan, even if the Company's market capitalization increases significantly.

149. Subsequently, the Company hit additional valuation milestones, thereby entitling Plan participants, including the Individual Defendants named herein, "a minimum of $81.0 million up to a hypothetical maximum of $195.0 million."

150. In a January 17, 2022 *New Yorker* article, it was revealed that Dr. Wang was entitled to a share of the awards granted under the Plan. Defendant Gussin was quoted in the article as stating that the Company's compensation arrangement with Dr. Wang was "not typical, I'll say you that. And I'm not thrilled with that aspect of things."

151. On March 17, 2023, the Company announced that all non-employee directors were being removed as beneficiaries from the Plan. The Company did not announce whether this impacted the compensation of individuals such as Drs. Wang and Burns.

Citizen's Petition

152. The Citizen's Petition was filed with the FDA on approximately August 18, 2021, on behalf of Drs. David Bredt and Geoffrey Pitt. The petition centered on "grave concerns about the quality and integrity of the laboratory-based studies surrounding [simufilam] and supporting claims for its efficacy." Attached to the petition was a 42-page technical report created by Drs.

Bredt and Pitt which "shows a series of anomalies that are suggestive of systematic data manipulation and misrepresentation."

153. As the petition asserts, "[a]ll of the foundational science supporting Cassava's claims about Simufilam's use for Alzheimer's disease comes from a series of papers with two common co-authors (Dr. Hoau-Yan-Wang at City University of New York and Dr. Lindsay Burns of Cassava)." The petition continues that Cassava was able to leverage these series of papers by Drs. Wang and Burns "to obtain NIH grants and to open an Investigational New Drug (IND) application to study Simufilam." And yet, "[n]o other lab has confirmed Cassava's research connecting Filamin A to Alzheimer's Disease, nor has any other lab confirmed that Simufilam binds or modifies Filamin A or has effects in Alzheimer's Disease models."

154. Based upon a "close review of the data and analyses in the foundational research papers and Cassava's recent publications" the Citizen's Petition identified three primary areas of concern:

a. The underlying papers of Drs. Wang and Burns involve extensive use of Western blot analyses to support theirs claims connecting Simufilam to Alzheimer's Detailed analysis of the western blots in the published journal articles shows a series of anomalies that are suggestive of systematic data manipulation and misrepresentation.
b. Some of the foundational studies published by Drs. Wang and Burns make claims about Simufilam's effects in experiments conducted on postmortem human brain tissue. The methodology allegedly used in these experiments defies logic, and the data presented against have hallmarks of manipulation.
c. Cassava's presentation of clinical biomarker data from the Phase 2b trials raises questions about the validity of the data. The CSF samples in the study were first analyzed by an outside lab, which found that Simufilam was ineffective in improving the primary biomarkers end point and high variability in other biomarkers. But Cassava had these samples analyzed again and this time reported that Simufilam rapidly and robustly improved a wide array of biomarkers. Cassava has not fully published the data from this reanalysis, but a presentation post that it published on July 26, 2021, which appears to describe aspects of that work, shows signs of data anomalies or manipulation."

155. Following the publication of the petition, other scientists began raising similar concerns regarding Cassava's findings. In a supplement to its petition titled "Third Supplement to Citizen's Petition Associated with Cassava Sciences, Inc." and dated November 17, 2021, the petitioners noted that "the scientific community began a comprehensive review of Dr. Wang's research and **29 papers have already been red flagged on Pubpeer.com."** The supplement also noted that 9 of these flagged papers were "co-authored by Dr. Lindsay Burns" and three were "co-authored by Dr. Steven E. Arnold, a member of Cassava's Scientific Advisory Board."

156. In this supplement, Drs. Bredt and Pitt revealed themselves as the anonymous petitioners. Drs. Bredt and Pitt were classmates at Johns Hopkins University School of Medicine in 1993. Dr. Bredt has published over 255 papers, which in total have been cited more than 75,000 times. Meanwhile, Dr. Pitt has served as a member of the Society for Neuroscience since 2001, received over ten NIH grants throughout his career, and serves on research misconduct committees at academic institutions.

157. In a *New Yorker* article titled "Jordan Thomas's Army of Whistle-Blowers," Drs. Bredt and Pitt discussed their research into Cassava's research process and the trail of evidence that resulted in them filing a petition with the FDA and SEC and taking a short position on Cassava's stock. Dr. Bredt became suspicious of Cassava's roaring stock price after the Company announced the success of "a trial without a placebo." Dr. Bredt noted that it is "human nature to want things to work," particularly something that could provide as much value as an Alzheimer's disease drug. But he was shocked when he read Drs. Wang's and Burns' research papers, stating that the pair "were making statements that were incompatible with biology and with pharmacology."

158. Dr. Bredt shared his concerns regarding Cassava's research with Dr. Pitt, who "echoed Bredt's skepticism." On July 26, 2021, Dr. Bredt attended the Alzheimer's Association International Conference (the "AAIC") in Denver where he obtained some of Cassava's display materials and shared them with Dr. Pitt. On their review, the doctors shared skepticisms about Cassava's western blot test—it looked as if "they had been tweaked by a program such as Photoshop." The pair's skepticism grew. Next, they turned their attention to Cassava's September 2020 press release announcing the new results of its Phase 2b re-analysis. "Now suddenly, [simufilam is] the best drug! That just doesn't happen," remarked Dr. Pitt. The doctors also learned that just before announcing its re-analysis of the Phase 2b data, Cassava implemented a new compensation scheme with lucrative rewards for Defendant Barbier and other senior executives if "the company's stock met certain benchmarks." Cash bonuses would mature if the Company met specific valuations for 20 consecutive business days.

159. Prior to filling the Citizen's Petition, Drs. Bredt and Pitt shared their concerns with ten prominent experts, including "Thomas Südhof, of Stanford, who received the Nobel Prize in 2013; Roger Nicoll, of the University of California, San Francisco; and Don Cleveland, of the University of California, San Diego." To the surprise of Drs. Bredt and Pitt, Cassava had gained no notoriety or reputation amongst experts, even though the Company's claims and research would be field altering if true. All ten of the experts told Drs. Bredt and Pitt they had never even heard of Cassava. Dr. Pitt noted that most reactions by the experts were "***Oh, my God, how could they get away with this?***" (Emphasis added.) To Dr. Pitt and the others, "[i]t appeared that someone had tried to crop [the Western-blot images] and cut out little pieces of one and put them in another."

160. On August 27, 2021, Dr. Elizabeth Bik, a renowned forensic image consultant, detailed her concerns about Drs. Wang's and Burns' research in a blog post titled "Cassava

Sciences: Of Stock and Blots." Dr. Bik "look[ed] at the problematic photos included in the [Citizen's Petition] and ***agree[d] with most of those concerns.***" (Emphasis added.) According to Dr. Bik, "At least five other articles from the Wang lab at CUNY appear to show image concerns as well. These papers might not be directly related to Simufilam research, but they are still indirectly connected to Cassava Sciences and its drug candidates." She ended, noting that "the problems in these additional articles raise concerns about Western blots and perhaps also other data from [Dr. Wang's] lab spanning a period of 15 years."

161. Dr. Bik asserts that she does "not own any Cassava Sciences shorts or stock" and that she "was not paid by any person or organization to investigate these allegations, to analyze these papers, or to write this post."

162. In a *New Yorker* profile of Dr. Bik, Renee Hoch, one of the editors of *PLOS One*, told journalist that "of the first hundred and ninety or so of Bik's cases that the team had resolved, forty-six percent required corrections, around forty-three percent were retracted, and another nine percent received 'expressions of concern.'"

163. Most experts in the field have been appalled by the research misconduct displayed by Cassava and Drs. Wang and Burns. As put by Dr. Bredt, "In my thirty-five years of research, I've never seen such a long trail of apparently clear misrepresented scientific data."

164. With advancing computer software, photos and data, such as Western blot data, have become easier and easier to manipulate. In 2018, the United States Department of Health and Human Services' Office of Research Integrity (the "ORI") published an article in its Spring 2018 Newsletter noting that "[w]idespread and easy access to digital image processing software, such as Photoshop, has increased the odds of manipulated images appearing in all types of publications, including scientific journals."

165. Indeed, the ORI outlaws such scientific misconduct under 42 C.F.R. Part 93, defining research misconduct as the "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." Under the ORI's very own guidelines, the image manipulation unveiled by Drs. Bredt and Pitt seemingly indicate that Cassava's scientists Drs. Wang and Burns had engaged in research misconduct.

Substantive Findings Contained Within the Citizen's Petition

166. The Citizen's Petition laid out "a long-standing pattern of seemingly intentional data manipulation and misrepresentations in scientific papers." It analyzed Western Blot Data that Drs. Wang and Burns had utilized in over 15 years of research and publication. The Citizen's Petition calls into question the science Cassava and the Doctors used to support trials for simufilam and receive over 5 million in NIH grants for preclinical/clinical studies and the over $250 million in public fundraising by Cassava. The Citizen's Petition identified three areas of major concern: (1) the integrity of Western Blot Data; (2) the integrity of analyses involving human brain tissue; and (3) the integrity of Clinical Biomarker Data.

1. Major Concern: Integrity of Western Blot Data

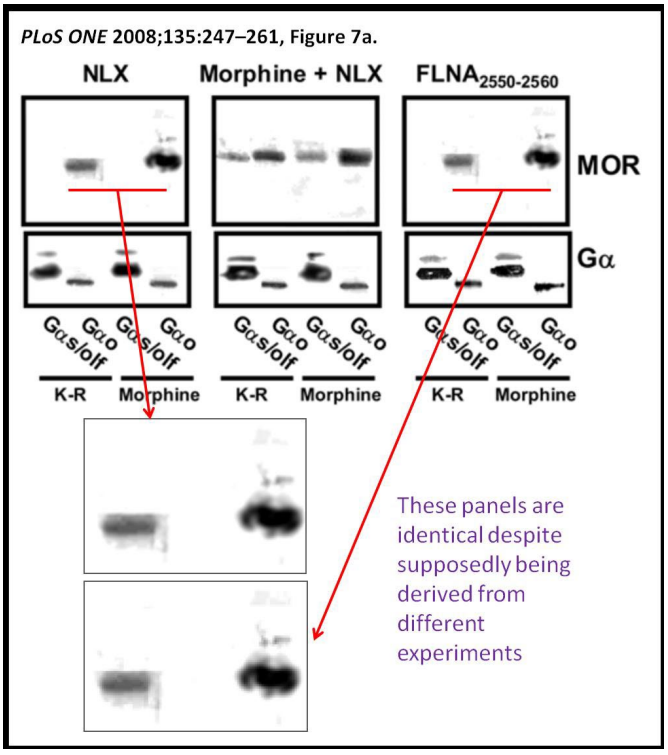
167. First, the Citizen's Petition elucidated concerns regarding Drs. Wang's and Burns' manipulation of Western blotting data. Western blotting refers to the technique where "proteins from tissue samples are separated on 'gels' in a series of vertical lanes; the proteins are then transferred to a paper-like membrane, and antibodies are used to detect specific proteins on the membrane, producing an image of specific proteins or 'bands.'" Typically, each band produced will have a "slightly different shape."

168. Regarding Drs. Wang's and Burns' used of Western blot data, the Citizen's Petition notes that the data presented by them are "almost always overexposed and highly processed"—

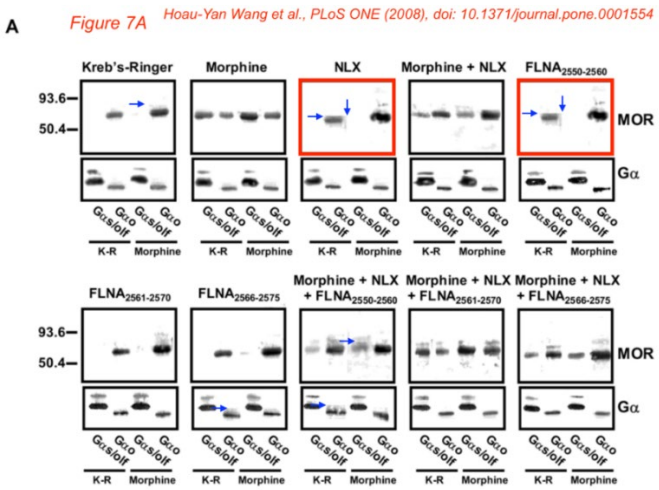
two key signs often seen in previous cases of data manipulation. The Citizen's Petition identified four examples from that present "strong evidence of image manipulation," two of which were essential to proving simufilam's effectiveness and are discussed below.

a. ***Example: Reused/Misrepresented Western Blot; PLOS ONE 2008;3:e1554 – Figure 7a.***

169. The Citizen's Petition identified Drs. Burns' and Wang's co-authored paper "High-Affinity Naloxone Binding to Filamin A Prevents Mu Opioid Receptor-Gs Coupling Underlying Opioid Tolerance and Dependence," as having "suggestive signs" which "appear to show spliced experiments." The Citizen's Petition asserts that the article presents "a series of overexposed and selectively cropped gels," intended to make it appear that two separate experiments were instead done simultaneously. Figure 7a (below) "shows two IDENTICAL panels (red arrows) for what are reported as different experiments." Bands having identical appearances "could not have occurred by chance."



170. The Citizen's Petition was not alone in its concern. In an August 27, 2021 post on Science Integrity Digest, Dr. Bik explained that "**Figure 7A** of the *PLOS ONE* 2008 paper contains two blots that appear to look identical. In addition, some sharp background transitions suggestive of splicing may be visible." Below, Dr. Bik marked in red boxes the two blots that appear to be identical and marked with the blue arrows where signs of splicing appear.



171. These concerns demonstrated by the photographic evidence above would result in a March 30, 2022 retraction by *PLOS One*, alongside four other papers authored by Drs. Wang and Burns. In part, the journal retraction noted concerns about data manipulation in the Doctors' Western blot data and that the "raw, original" data provided did not alleviate such concerns.

b. *Example: Band Insertion Into Western Blots – Journal of Neuroscience 2012*

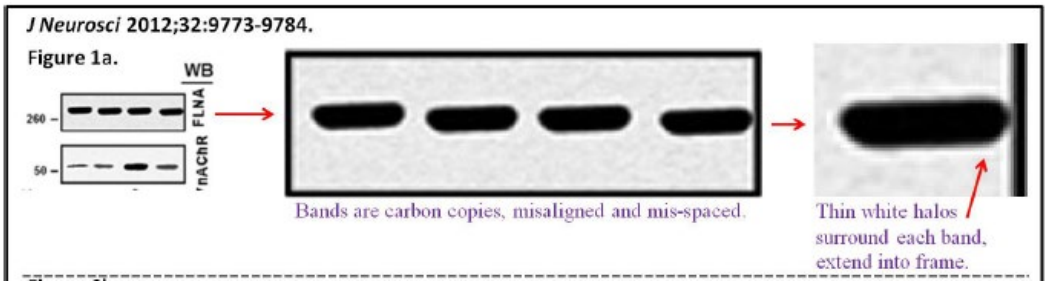
172. The Citizen's Petition detailed issues in Drs. Wang's and Burns' 2012 paper in the *Journal of Neuroscience* titled "Reducing amyloid-related Alzheimer's disease pathogenesis by a small molecule targeting filamin A." This paper was funded by Pain Therapeutics, and as the Citizen's Petition notes, "appears to contain a collection of questionable western blots." Evidence is suggestive of "duplicated and transposed bands." The Citizen's Petition and Dr. Bik detailed concerns regarding Figures 1A, 6B, 8, 9A, 11A, and 12A.

173. On August 27, 2021, Dr. Bik wrote a concurrence blog noting she "agree[d] with" the Citizen's Petition's "concerns" regarding "several Western blots in the 2012 *J Neurosci* paper" that "show oversaturated bands with little background detail, irregularly spaced bands, and bands that look remarkably similar."

174. Figure 1A of the paper showed four consecutive blots that looked "essentially identical.": Regarding Figure 1A (below), the Citizen's Petition described in further detail that:

> the four Filamin A bands in the top set are more similar to each than can be expected by chance and appear to be duplicates. The images at right are magnified, showing that the pixels containing the bands are ***essentially identical***. Additionally, the blots are not aligned and the spacing is irregular.

(Emphasis added.)



175. Further, the Citizen's Petition noted that the "thin white halos surrounding each band are concerning. There are optical reasons why a halo… could occur, but this artifact is ***most common when components from multiple images are combined using photo editing software***." (Emphasis added.)

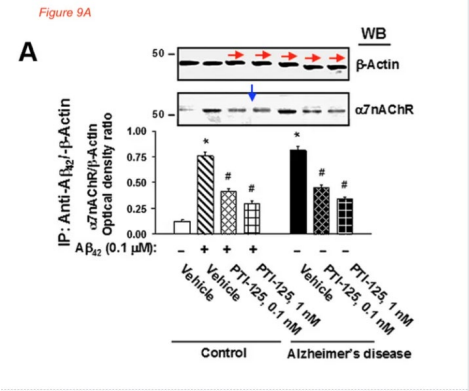
176. Dr. Bik concurred, noting in an August 2021 post on PubPeer that "the FLNA blots appear over-saturated, similar in shape, and irregularly spaced." While she called on "the authors [to] show the original, uncropped blots," such request was never met.

177. Regarding Figure 6B (below), the Citizen's Petition noted, "The four rightmost bands appear to be identical to each other. This degree of similarity is unlikely to occur by chance."

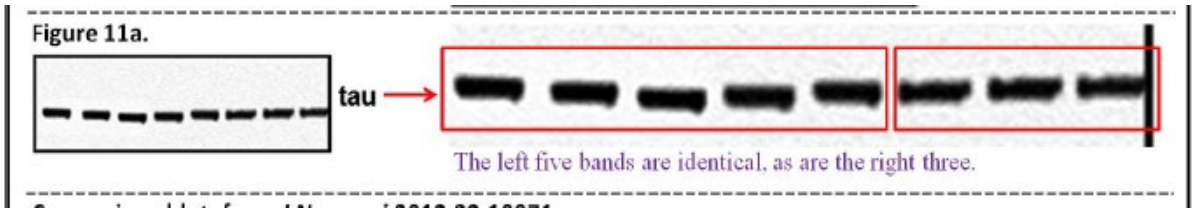
178. Dr. Bik noted similar concerns, explaining that "[a] detail shot of the IRb blot in Figure 6B shows similar irregular spacing and similarity in band shapes. Several bands have a particular, shoe-like appearance."

179. Regarding Figure 9A, the Citizen's Petition noted: "The five rightmost actin bands have a distinctive shape, ***but are nevertheless identical to each other***. ***That these bands all have apparently identical "dipper" shapes cannot occur by chance.*** As above, the thin white border surrounding each band is prominently seen again." (Emphasis added.)

180. Dr. Bik noted similar concerns, demonstrating in her own rendition of the diagram (below) that "five bands in the b-Actin blot look remarkably similar" (red arrows) and noted "a possible splice between lanes 3 and 4" (blue arrows).



181. Regarding Figure 11A, the Citizen's Petition stated: "The five leftmost tau bands appear to be identical to each other, AND the 3 rightmost tau bands appear to be identical to each other. ***These degrees of similarity are unlikely occur by chance***."

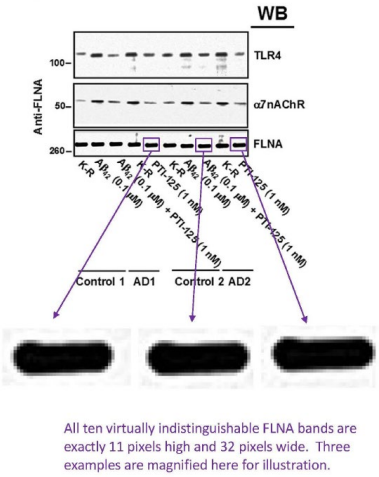


182. In Dr. Bik's opinion, "the left five bands look very similar to each other" and the "right three bands look very similar to each other."

183. Regarding Figure 12A, the Citizen's Petition stated:

> Figure 12A (below) of the Journal of Neuroscience paper, used human Alzheimer's disease tissue to establish the SavaDx biomarker and effects of PTI-125/simufilam. The ten filamin A (FLNA) ***bands appear identical in size and shape.*** As protein bands on Western blots typically have unique features, ***ten consecutive indistinguishable bands are exceedingly unlikely to occur by chance and were probably manually duplicated.***

(Emphasis added.)



184. The Citizen's Petition strongly concludes that while "each of these examples is concerning … together they form a pattern that strongly calls into question the integrity of this

publication. ***The work in question here serves as THE foundational research linking PTI-125 (Simufilam) to Alzheimer's disease***." (Emphasis added.) Notably, the Company leveraged the data in this paper "**to garner NIH grant AG060878 and open an FDA investigational new drug application to study PTI-125 (Simufilam) in Alzheimer's disease patients.**" (Emphasis in original.)

185. On December 17, 2021, the *Journal of Neuroscience* issued an Expression of Concern indicating that the article contained questionable data.

2. Major Concern: Integrity of Analyses Involving Human Brain Tissue

186. The foundation of Drs. Wang's and Burns' research stems from the idea that simufilam can bind to FLNA and restore FLNA to a healthy conformation. The doctors say that simufilam prevents a protein (β-amyloid) from phosphorylating with an enzyme (tau). Proving that simufilam can prevent tau-phosphorylation is complicated and, as the Citizen's Petition points out, Drs. Wang and Burns "proved" it through the use of "post-mortem human brain tissue" of subjects with Alzheimer's disease. Enzyme reactions require specific temperatures to occur. Naturally in the human body, enzymes "generally work best at body temperature—37°C." In Drs. Wang's and Burns' experiments, however, they were utilizing post-mortem brain tissue that had been frozen from months to even years at -80°C and warmed until about 4°C. The two key problems presented by this, however, are that (1) the tau enzyme likely would not have survived in the brain tissue frozen at -80°C, and (2) even if it had survived, it likely would not have phosphorylated at just 4°C. Or as put by Dr. Nicoll in the *New Yorker* article, "It's hard for me to imagine how you could get any life from that tissue. I mean, this is wild. It's zombie science!"

187. The "zombie science" was used in two foundational articles published by Drs. Wang and Burns: (1) "Reducing Amyloid-Related Alzheimer's Disease Pathogenesis by a Small

Molecule Targeting Filamin A," published in *Journal of Neuroscience*, 2012; (2) "PTI-125 binds and reverses an altered conformation of filamin A to reduce Alzheimer's disease pathogenesis," published in *Neurobiology of Aging*, 2017. Additionally, the Citizen's Petition makes clear that both of these articles utilized Western blot data, which had clear signs of manipulation.

Appendix

188. The Appendix of the Citizen's Petition laid out additional concerns, particularly about Drs. Wang's and Burns' 2008 *PLOS One* article and their 2017 *Neurobiology of Aging* article.

189. In the 2008 article, the Citizen's Petition notes "remarkably high affinity binding between Naloxone and Filamin A." The Citizen's Petition notes that because "Filamin A is present in the brain, it is puzzling why previous studies have not reported picomolar binding affinity for naloxone in brain."

190. Meanwhile, in the 2017 article the Citizen's Petition demonstrated "remarkably high affinity binding between PTI-125 and Filamin A." As shown below, the data features "shallow displacement" that is "highly unusual/unprecedented." Additionally, the Citizen's Petition demonstrated that the authors present a gel showing Filamin A that is suspicious because (1) there is a 100% reported "shift" of Filamin A in the diseased brains and (2) that data of isoelectric focusing gel usually does not look like the graph depicted below. Lastly, the Citizen's Petition critiqued the study as showing a "pattern of results [that] is unlikely to occur and suggests, at the least, the experiments were conducted incorrectly."

191. Overall, the Citizen's Petition notes that these observations "strongly call into question the assertion that PTI-125/simufilam alters the interaction between β-amyloid and any of its supposed targets."

3. Major Concern: Integrity of Clinical Biomarker Data

a. *The Re-analysis was Conducted by Dr. Wang's Lab*

192. The Citizen's Petition noted Cassava's double-blind placebo-controlled Phase II trial for simufilam was conducted to observe changes from baseline in cerebrospinal fluid ("CSF") biomarkers. Improvements in reported biomarkers would be demonstrative of the success of the drug at this phase in the trial. However, on May 15, 2020, Cassava reported "that [Phase II] missed its primary end points," suggesting the drug was ineffective.

193. This revelation had an immediate impact on Cassava's stock price, dropping it from a price per share of $8.11 at the close of trading on May 14, 2020, to a price per share of $2.12 at the close of trading on May 15, 2020.

194. Thus, as the Citizen's Petition notes, fortune seemed to strike Cassava when it retested the same patient samples. On September 14, 2020, the Company reported that the previous test had been performed by an external group and contained errors. But when Cassava had the samples retested and finalized with a different, outside academic lab, the Company now claimed that simufilam robustly improved all biomarkers.

195. The dramatic and positive results from the retesting spelled good news for Cassava stock prices. The Cassava's common stock price increased from $3.32 per share on September 11, 2020 to $7.75 per share on September 14, 2020. By September 18, 2020, Cassava shares began trading for over $10 per share.

196. The Citizen's Petition suspected that the Company had actually had Dr. Wang's lab conduct the re-analysis of the Phase 2b results, rather than the vaguely described "outside" and "academic" lab. This would prove to ultimately be correct.

b. *The Company's presentation of the Phase 2b results at the AAIC contained incorrect data*

197. On July 26, 2021, Cassava presented the re-analyzed Phase 2b results at the AAIC. However, as the Citizen's Petition would point out, Cassava presented incorrect data at the conference. The poster the Company utilized had data points that "[could not] be from the same data set." Represented in the picture above and taken directly from the Citizen's Petition, the Citizen's Petition explained:

> In Figure 5, one patient in the 100mg group… had a P-Tau181 level which increased from ~1.5 to 5 pg/ml during the 28-day treatment period, ~235% change from baseline. However, in figure 4 there is no data point in the 100 mg treatment groups showing a CFB >40%. If the correct data point (+235%) were averaged in with the other points in figure 4, any beneficial effect of 100 mg simufilam would likely have been negated.

198. Additionally, the Company published different results on ClinicalTrials.gov, where notably the 50 mg group had a -3.35 change while the 100 mg group had a -2.31 change. Thus, in government published data, the 50 mg group actually demonstrated a greater change. Cassava was able to reflect the 100 mg as having a greater change by ***removing*** seven individuals from the baseline of the groups. The Citizen's Petition's critique of this data point would prove to be correct.

False and Misleading Statements Made During the Relevant Period

September 14, 2020 Press Release

199. On September 14, 2020, the Company issued a press release on a Form 8-K filed with the SEC, reviewed by Dr. Friedmann and Defendants Barbier and Schoen, announcing the final results of its Phase 2b clinical study of simufilam. The press release contained false and misleading statements attributed to Defendants Friedmann and Barbier and stated, in relevant part:

> Cassava Sciences, Inc. (Nasdaq: SAVA) today announced final results of a Phase 2b study with its lead drug candidate, simufilam, in Alzheimer's disease. In a clinical study funded by the National Institutes of Health (NIH), ***simufilam***

significantly improved an entire panel of validated biomarkers of disease in patients with Alzheimer's disease. The ability to improve multiple biomarkers from distinct biological pathways with one drug has never been shown before in patients with Alzheimer's disease. Study results are expected to be published in a peer-reviewed publication. Simufilam is the first of a new class of drug compounds that bind to a protein called Filamin A.

"Filamin-binding molecules are new to Alzheimer's research and may represent an important advance if these data can be replicated in larger studies," said Jeffrey Cummings, M.D., Sc.D., Founding Director of the Cleveland Clinic Lou Ruvo Center for Brain Health, and Chambers Professor of Brain Science at the University of Nevada, Las Vegas. "I am pleased to see early evidence of disease-modifying effects in patients with this investigational drug. The data appear to represent a step forward toward urgently needed treatments for Alzheimer's disease."
In addition, Alzheimer's patients treated with simufilam showed directional improvements in tests of remembering new information, versus patients on placebo. ***Improvements in cognition correlated most strongly with decreases in P-tau181, a biomarker that, when elevated, leads to tangles in the brain. Simufilam decreased brain levels of Ptau-181 by 8-11%, versus placebo.***

In this study, ***Alzheimer's patients treated with 50 mg or 100 mg of simufilam twice-daily for 28 days showed statistically significant ($p<0.05$) improvements*** in biomarkers of disease pathology, neurodegeneration and neuroinflammation, versus Alzheimer's patients who took placebo. In addition, Alzheimer's patients treated with simufilam showed directional improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo (Effect Sizes 46-17%). ***Cognitive improvements correlated most strongly (R2=0.5) with decreases in P-tau181. The study achieved a 98% response rate, defined as the proportion of study participants taking simufilam who showed improvements in biomarkers.***

"The clinical data suggest simufilam may be slowing disease progression in Alzheimer's patients," said Nadav Friedmann, PhD/MD, Chief Medical Officer, Cassava Sciences. "This exciting possibility will need to be evaluated in future collaborations with patients, physicians, advisors and others."

"Other than a few drugs to help ease the decline, there's really nothing out there to treat people with Alzheimer's," said ***Remi Barbier, Chairman, President & CEO, Cassava Sciences. "The improvement on multiple biomarkers in this clinical study is a first*** and offers hope that simufilam has potential to become a transformative treatment for people with Alzheimer's disease."

(Emphasis added.)

200. The press release assured that "[a]ll CSF samples ***were sent to outside labs for bioanalysis."*** Additionally, it stated that "[a]n academic lab generated final results."

201. Regarding the previous Phase 2b results, the press release stated:

> As previously disclosed, an initial bioanalysis by a different lab showed highly anomalous data, e.g., huge swings (in both directions) in levels of biomarkers, as well as biomarkers moving in opposite directions in the same patients, all in the group who took placebo for 28 days. ***With its validity in question, the initial bioanalysis serves no useful purpose.***

(Emphasis added.)

202. The press release emphasized that the new results met expectations, concluding:

> **Phase 2b Study Conclusions**
>
> A small, well-controlled study of simufilam showed promising treatment effects in patients with mild-to-moderate Alzheimer's disease. In this study, simufilam treatment over 28 days improved an entire panel of validated biomarkers of Alzheimer's disease, decreased measurements of neuroinflammation, showed a 98% responder rate, appears safe and well-tolerated, and appears to benefit cognition. ***Importantly, the data are consistent with prior clinical and preclinical results, the drug's mechanism of action and over 10 years of basic research.***

(Emphasis added.)

203. The statements in ¶¶199-202, including those made by Dr. Friedmann and Defendant Barbier, were false and misleading and failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests

which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequateinternal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

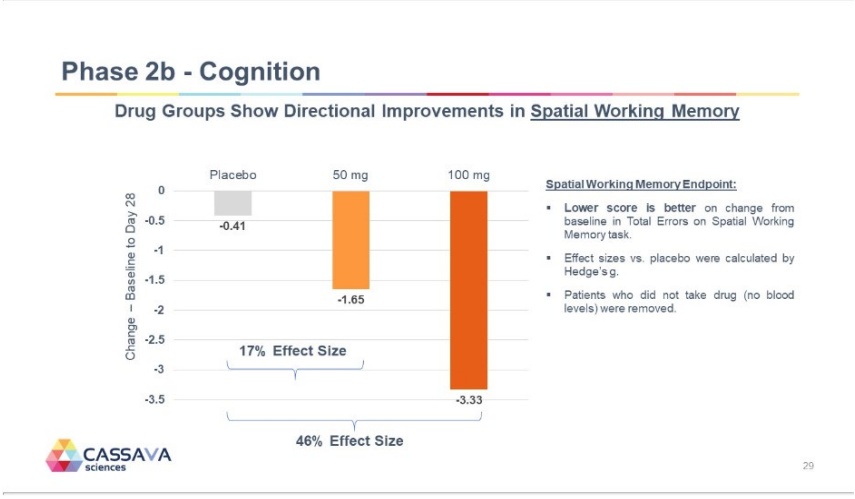
September 14, 2020 Presentation and Conference Call

204. Alongside the press release, the Company held a conference call with investors and attached to the Form 8-K the accompanying the presentation titled "Final Results of a Phase 2b Study of Sumifilam[11] [sic] in Alzheimer's Disease." The presentation doubled-down on the purported irregularities of the May 15 results, stating "an outside lab conducted an initial bioanalysis of the Phase 2b study***. Biomarker data received from the lab made no sense.***" (Emphasis added.)

205. The presentation further emphasized that **"*[a]n academic lab conducted a second, final bioanalysis of the Phase 2b study.*"** (Emphasis added.)

206. Additionally, the presentation included the following side, representing the positive impact simufilam has on spatial working memory, showing a ***-1.65 result in the 50 mg group and a -3.33 result in the 100 mg group.*** (Emphasis added.)

[11] The Company in all corporate communications referred to "simufilam" as "sumifilam" until approximately January 2021.



207. On slide 26 of the presentation, the Company represented that "Sumifilam ***significantly improved an entire panel of AD-related biomarkers***." (Emphasis added.) Likewise, during the conference call, Defendant Barbier himself repeated this phrase.

208. Defendant Barbier also explained why the Company believed the second biomarker analysis of the Phase 2b data was legitimate, stating:

> ***An academic lab conducted a second and final biomarker analysis of the phase 2 data. The academic lab showed what we consider to be valid, proper and expected data in placebo patients.*** The data from this lab shows modest swings, [inaudible] swings of course, maybe 4-6% on average, in level, in changes in levels of biomarkers over 28 days, but more importantly they showed biomarkers that generally moved in the same direction and robust statistical correlations among changes in levels of biomarkers. ***For these reasons both ourselves and our advisors and pretty much anyone we've shown all the data to have confirmed that the second bioanalysis is a valid analysis.***

(Emphasis added.)

209. Moreover, Dr. Burns emphasized the respect Cassava's pre-clinical and clinical research had garnered, stating:

> ***All this science, now on slide 14, has been published in peer reviewed journals starting in 2012 showing the filamin A was critical to this toxic signaling, 2017 showing that filamin A was in an altered conformation***, and this year with the publication of our phase 2a clinical results. Sumifilam [*sic*] has also stood up to many peer reviewed NIH grant applications and received multiple NIH grant awards. ***So with all this science holding, holding it up, we, moving to slide 15, we***

were able to come up with the clinical hypothesis, can sumifilam provide early clinical evidence of disease modifying effect in a well-controlled study.

210. The statements in ¶¶ 204-209 were false and misleading and failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

211. Additionally, the statement in ¶ 206 was false and misleading because it misstated and misrepresented the data. In particular, the misstated results stated that the 100 mg group had a better score than the 50 mg group (as a lower score is considered to be better.) However, the actual results reflect that the 50 mg group scored a -3.35, while the 100 mg group scored a -2.31—rather than the purported -1.65 for the 50 mg group and the -3.33 for the 100 mg group. Moreover, these dosage groups were compromised by inequivalent baseline measurements. During the testing,

seven individuals had to be removed from the baseline Spatial Working Memory test in both groups, thereby giving those groups a performance advantage over the Placebo group.

212. Additionally, the statement in ¶ 206 was false and misleading because it misled investors that measurements of "biomarkers" was proof of drug efficacy.

213. Additionally, the statement in ¶ 208 was materially false and misleading because the Company was concealing the fact that it was Dr. Wang's lab who had conducted the reanalysis.

September 15, 2020 H.C. Wainwright 22nd Annual Global Investment Conference

214. On September 15, 2020, Defendant Barbier represented the Company at the H.C. Wainwright 22nd Annual Global Investment Conference. At the conference, Defendant Barbier gave a presentation in which he stated that simufilam "targets both neurodegenerative and neuroinflammation in Alzheimer's Disease and it does so by binding to a single target. ***You don't have to take our word for it. The underlying science is published in a number of peer reviewed journals and benefits from multiple recent clinical and non-clinical grants from the NIH***." (Emphasis added.)

215. Defendant Barbier would go on to again emphasize during his presentation that ***"Again you don't have to take our worked for it. The underlying science for simufilam has been subject to the scrutiny of many experts in the field including the [NIH],*** which have awarded us over $10 million in research grants." (Emphasis added.)

216. Defendant Barbier furthered that "a ***well-controlled Phase 2b study in simufilam showed promising treatment effects*** in a population of mild to moderate [Alzheimer's Disease] patients… ***overall we feel that the dataset around simufilam really highlights this drug's potential as the disease modifying drug candidate for Alzheimer's Disease.***" (Emphasis added.)

217. Defendant Barbier's statements in ¶¶ 214-216 were false and misleading because they failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

November 4, 2020 Form 8-K

218. On November 4, 2020, the Company filed a Form 8-K with the SEC with a press release and presentation attached.

219. The press release, titled "Cassava Sciences Announces Additional Clinical Data from a Phase 2b Study of Sumifilam [sic] in Alzheimer's Disease," again re-emphasized the success of the September 14, 2020 results, stating:

Previously Announced Clinical Phase 2b Data

> ***As previously announced in September 2020, sumifilam was safe and well-tolerated, with no drug-related patient discontinuations. Alzheimer's patients treated with 50 mg or 100 mg sumifilam twice-daily for 28 days showed statistically significant (p<0.05) improvements in eight biomarkers of disease pathology, neurodegeneration and neuroinflammation, versus Alzheimer's patients who took placebo. In addition, Alzheimer's patients treated with sumifilam showed improvements in validated tests of Episodic Memory and Spatial Working Memory, versus patients who took placebo*** (Effect Sizes 17-46%). Cognitive improvements correlated most strongly (R2=0.5) with decreases in P-tau181, a biomarker that leads to tangles in the brain. Sumifilam decreased brain levels of Ptau-181 by 8-11%, versus placebo. The study achieved a 98% response rate, defined as the proportion of study participants taking sumifilam who showed improvements in biomarkers.

(Emphasis added.)

220. Additionally, November 4, 2020 press release again emphasized that "***the underlying science for sumifilam is published in peer-reviewed journals,*** including *Journal of Neuroscience, Neurobiology of Aging, Journal of Biological Chemistry, Neuroimmunology and Neuroinflammation* and *Journal of Prevention of Alzheimer's Disease*." (Emphasis added.)

221. Alongside the press release, was the attached presentation titled "Sumifilam Significantly Improves Eleven CSF Biomarkers in a Randomized, Placebo-controlled, One-month Clinical Trial in Alzheimer's Disease Patients." The presentation published results of the Phase 2b trial authored by Drs. Burns, Wang, and Friedmann. The presentation stated, in relevant part, "***[p]ublished preclinical and mechanism of action data support sumifilam's potential as a disease-modifying drug for AD that may also enhance cognition."*** (Emphasis added.)

222. On a slide titled "Study Conclusions," the presentation stated that "***Phase 2b treatment effects replicate prior clinical results and are consistent with published preclinical data and the drug's mechanism of action.***" (Emphasis added.)

223. The presentation also included the same slide and data represented in ¶ 207 and again showed a ***-1.65 result in the 50 mg group and a -3.33 result in the 100 mg group.*** (Emphasis added.)

224. The statements made in ¶¶ 218-223 were false and misleading because they failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

225. Additionally, the statement in ¶ 223 is false and misleading for the same reasons indicated in ¶ 212.

November 9, 2020 Form 10-Q

226. On November 9, 2020, the Company filed its quarterly report on a Form 10-Q with the SEC for the quarter ended September 30, 2020 (the "3Q20 Form 10-Q"). The 3Q20 Form 10-Q was signed and reviewed by Defendants Barbier and Schoen and stated the following:

> Our lead therapeutic product candidate, sumifilam, is a proprietary small molecule (oral) drug. Sumifilam targets an altered form of a protein called filamin A ("FLNA") in the Alzheimer's brain. ***Published studies have demonstrated that the altered form of FLNA causes neuronal dysfunction, neuronal degeneration and neuroinflammation.***
>
> We believe sumifilam improves brain health by reverting altered FLNA back to its native, healthy conformation, thus countering the downstream toxic effects of altered FLNA***. We have generated and published experimental and clinical evidence of improved brain health with sumifilam.*** Importantly, sumifilam is not dependent on clearing amyloid from the brain. Since sumifilam has a unique mechanism of action, we believe its potential therapeutic effects may be additive or synergistic with that of other therapeutic candidates aiming to treat neurodegeneration.
>
> ***Sumifilam has demonstrated a multitude of beneficial effects in animal models of disease, including normalizing neurotransmission, decreasing neuroinflammation, suppressing neurodegeneration, and restoring memory and cognition.***
>
> * * *
>
> **Phase 2a Study**
>
> In 2019, we completed a small, first-in-patient, clinical-proof-of-concept, open-label Phase 2a study of sumifilam in the U.S., with substantial support from the *National Institute on Aging* ("NIA"), a division of NIH. Drug was safe and well-tolerated in this study. ***Treatment with sumifilam for 28 days significantly improved key biomarkers of Alzheimer's pathology, neurodegeneration and neuroinflammation (p<0.001).*** Biomarkers effects were seen in all patients in both cerebrospinal fluid ("CSF") and plasma.
>
> * * *
>
> On September 14, 2020, we reported positive Phase 2b clinical study results. Drug was safe and well-tolerated in this study***. Sumifilam significantly (P<0.05) improved an entire panel of validated biomarkers of disease in patients with Alzheimer's disease compared to a placebo group. In***

> ***addition, Alzheimer's patients treated with sumifilam showed directional improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo*** (Effect Sizes 46-17%). Cognitive improvements correlated most strongly (R=0.5) with decreases in levels of P-tau181 in CSF. The study achieved a 98% response rate, defined as the proportion of study participants taking sumifilam who showed improvements in biomarkers. ***Importantly, we believe these data are consistent with prior clinical and preclinical results, the drug's mechanism of action and over 10 years of basic research.***

(Emphasis added.)

227. The statements made in ¶ 226 were false and misleading because they failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

November 13, 2020 Underwriting Agreement

228. On November 13, 2020, the Company announced that it had entered into an underwriting agreement in which it agreed to sell 9,375,000 shares of common stock for $75 million, at a price of $8.00 per share. The Company announced this just a month after the results of the Phase 2b analysis resulted in the Company's stock price increasing by over 100%..

February 2021 Press Releases

229. On February 2, 2021, the Company announced the results of an interim analysis from an open-label study of simufilam. The press release contained statements attributed to Defendant Barbier and Dr. Friedmann, and stated, in relevant part:

> Cassava Sciences, Inc. (Nasdaq: SAVA) today announced results of an interim analysis from an open-label study of simufilam, its lead drug candidate for the treatment of Alzheimer's disease. Patients' cognition and behavior scores both improved following six months of simufilam treatment, with no safety issues.
>
> In a clinical study funded by the National Institutes of Health and conducted by Cassava Sciences, six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6. In these same patients, simufilam also improved dementia-related behavior, such as anxiety, delusions and agitation, by 1.3 points on the Neuropsychiatric Inventory, a 29% mean improvement from baseline to month 6.
>
> Alzheimer's is a progressive disease. Over time, a patient's cognition will always worsen. "Experience based on longitudinal studies of ambulatory patients with mild to moderate Alzheimer's disease suggest that scores on ADAS-cog decline by 6 - 12 points per year", according to FDA's Prescription Information sheet for ARICEPT® (donepezil), a drug approved for the treatment of dementia of the Alzheimer's type1.
>
> ***"We could not be more pleased with these interim results," said Remi Barbier, President & CEO. "We would have been satisfied to show simufilam stabilizes cognition in patients over 6 months. An improvement in cognition and behavior tells us this drug candidate has potential to provide lasting treatment effects for people living with Alzheimer's disease. It's an exciting development."***
>
> The safety profile of simufilam in the interim analysis was consistent with prior human studies. There were no drug-related serious adverse events. Adverse events were mild and transient.

> ***"Today's data once again suggests simufilam could be a transformative, novel therapeutic," added Nadav Friedmann, PhD, MD, Chief Medical Officer. "It appears the drug's unique mechanism of action has potential to provide a treatment benefit following 6 months of dosing."***
>
> * * *
>
> ***Cassava Sciences believes today's data and prior clinical results support advancing simufilam into a Phase 3 clinical program in Alzheimer's disease.*** Initiation of a Phase 3 trial remains on schedule for 2nd half 2021.
>
> * * *
>
> Simufilam is a proprietary, small molecule (oral) drug that restores the normal shape and function of altered filamin A (FLNA), a scaffolding protein, in the brain. Altered FLNA in the brain disrupts the normal function of neurons, leading to Alzheimer's pathology, neurodegeneration and neuroinflammation. ***The underlying science for simufilam is published in peer-reviewed journals, including Journal of Neuroscience, Neurobiology of Aging, Journal of Biological Chemistry, Neuroimmunology and Neuroinflammation and Journal of Prevention of Alzheimer's Disease.***

(Emphasis added.)

230. Following this announcement, the price per share of the Company's common stock skyrocketed from $22.99 at close on February 1, 2021 to $55.44 at the closing of trade on February 2. By close on February 3, 2021, the price per share of the Company's common stock was $87.95, an increase of approximately 383% from its February 1, 2021 price.

231. On February 8, 2021, Cassava issued another press release announcing, "Significant Program Progress and Expected Key Milestones in 2021 for its Clinical Program in Alzheimer's Disease." The press release contained a statement attributed to Defendant Barbier and stated, in relevant part:

> "***We started 2021 with tremendous momentum, led by results of a 6-month interim analysis from an open-label study of simufilam***, our drug candidate for Alzheimer's disease," ***said Remi Barbier***, President & CEO. "I believe the rest of the year may be equally exciting."
>
> Cassava Sciences' strategic focus for 2021 is to advance simufilam in a Phase 3 clinical program in Alzheimer's disease, to expand drug manufacturing capabilities in support of the clinical program, and to continue to lead the Company to deliver the full potential of its product portfolio.

Cassava Sciences' 2021 Scientific and Clinical Outlook

* * *

Expected progress and key milestones in 2021 across Cassava Sciences' product portfolio are summarized below.

- ***Based on recent positive clinical results*** and inbound demand from clinical sites, patients, and their caregivers, Cassava Sciences plans to expand the size of the ongoing open-label study of simufilam. The target enrollment will be increased by up to 50 additional patients with mild-to-moderate Alzheimer's disease, for a total target enrollment of up to 150 patients.

- Cassava Sciences has enrolled approximately 80 patients in the open-label study to date. To accommodate increased enrollment, the Company plans to open new clinical sites across the U.S. and Canada.

- Cassava Sciences expects to announce results of a second interim analysis of the ongoing open-label study when approximately 50 patients complete 12 months of drug treatment. This second interim analysis is expected to include clinical data around long-term safety, cognition and Alzheimer's-related behavior.

- Cassava Sciences plans to initiate a 6-month, double-blind, randomized, placebo-controlled study in patients with Alzheimer's disease who complete at least one year of open-label treatment with simufilam. This is a Cognition Maintenance Study (CMS), in which patients who complete one year of open-label treatment will subsequently be randomized (1:1) to simufilam or placebo for six months. The CMS is designed to compare simufilam's effects on cognition and behavior in patients who continue with drug treatment versus those who discontinue drug treatment. For ethical and other reasons, patients who successfully complete the six-month CMS will have the option to receive open-label simufilam.

- ***Cassava Sciences' clinical and regulatory strategy for simufilam is progressing as planned. In January 2021, the Company concluded a successful End-of-phase 2 (EOP2) meeting with the U.S Food and Drug Administration (FDA). The purpose of the EOP2 was to gain general agreement around a Phase 3 program to treat Alzheimer's disease dementia.***

- As a result of the EOP2 meeting, Cassava Sciences believes its clinical program for simufilam is green-lighted to commence a large, Phase 3 clinical program in patients with Alzheimer's disease, pending official FDA meeting minutes of the EOP2 meeting.

- Cassava Sciences plans to initiate a Phase 3 program of simufilam in Alzheimer's disease in the second half of 2021.

- Cassava Sciences' Phase 3 program for simufilam consists of two large, double-blind, randomized, placebo-controlled studies of simufilam in patients with mild-to-moderate Alzheimer's disease dementia. The Company expects to announce details of its Phase 3 program in Q1 2021, pending official FDA meeting minutes of the EOP2 meeting.

- Cassava Sciences' first Phase 3 study will evaluate disease-modifying effects in Alzheimer's disease patients over 18 months. The goal of this study is to show a slower rate of decline in cognition and daily function in patients treated with simufilam, compared to patients treated with placebo.

- Cassava Sciences' second Phase 3 study will evaluate symptomatic improvement in Alzheimer's disease patients over 6 months. The goal of this study is to show improvement in cognition and daily function in patients treated with simufilam, compared to patients treated with placebo.

- Cassava Sciences believes its manufacturing strategy is on-track to ensure sufficient drug supply for a Phase 3 program, including both drug substance (i.e., active ingredient) and drug product (i.e., oral tablets).

- Cassava Sciences expects to conclude a long-term, commercial drug supply agreement for simufilam with a contract manufacturing organization. The goal is to ensure the integrity of the drug supply chain on a worldwide basis, in compliance with FDA standards.

- Cassava Sciences expects to initiate a validation study with SavaDx, its investigational diagnostic for the detection of Alzheimer's disease.

- Cassava Sciences is in discussions with scientific and clinical advisors about potentially expanding therapeutic indications for simufilam outside of Alzheimer's disease, but still within neurodegenerative conditions.

Other Expected Milestones and Announcements for 2021

- ***Cassava Sciences expects to announce publication of Phase 2b results in a peer-reviewed technical journal.***

- Net cash use for full-year 2021 is expected to be in the range of $20 to $25 million, depending on enrollment rates in its clinical programs and other factors. On December 31, 2020, unaudited cash and cash equivalents were approximately $93 million.

(Italicized emphasis added.)

232. Alongside the press release, the Company attached a corporate presentation dated "February 2021." Drs. Burns, Friedmann, and Kupiec authored the presentation. The presentation emphasized that the following were "***key drivers of [Cassava's] clinical development program:***

- ***A decade of research in basic biology***
- ***Clear scientific rationale***
- ***Published pre-clinical results***
- ***Well-understood mechanism of action***
- Clean safety profile
- ***Evidence of target engagement in patients***
- ***Unprecedented CSF biomarker data***
- ***Phase 2b clinical results***
- ***Early data on cognition and behavior***
- Successful End-of-Phase 2 meeting with the FDA."

(Emphasis added.)

233. Further, the presentation stated that "***published preclinical data and mechanism of action studies support simufilam's potential as a disease-modifying drug for [Alzheimer's Disease] that also provides symptomatic improvement***." (Emphasis added.)

234. The presentation stated on a slide titled "Clinical Development":

> 2019: ***positive results on CSF biomarkers of disease in an open-label Phase 2a study of simufilam in [Alzheimer's Disease] patients.***
>
> 2020: ***positive results on CSF biomarkers of disease in a double-blind, randomized, placebo-controlled Phase 2b study of simufilam in AD patients.***

235. More specifically, the presentation represented that ***"Biomarkers of Neuroinflammation Decreased Significantly in Both Drug Groups" and that "Phase 2b Results — Improved Blood-brain Barrier Integrity***."

236. The presentation included the same slide regarding "spatial working memory data" referenced in ¶ 206.

237. The presentation concluded that:

- ***Simufilam improved a panel of validated biomarkers of disease pathology, neuroinflammation and BBB integrity.***

* * *

- ***Phase 2b data replicate prior clinical results and are consistent with published preclinical data and mechanism of action studies.***

238. The statements made in ¶¶ 229-237 were false and misleading because they failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

239. Additionally, the statement made in ¶ 236 was false and misleading for the same reasons stated in ¶ 212.

February 10, 2021 Stock Offering

240. On February 10, 2021, Cassava announced an offering of its common stock priced at $49 per share. The Company sold 4,081,633 shares for a total of $200 million. On February 12, 2021, the Company completed the offering.

February 22, 2021 Press Release

241. On February 22, 2021, the Company issued a press release announcing a "Positive End-of-Phase 2 Meeting with FDA and Outlin[ing] a Pivotal Phase 3 Program for Simufilam in Alzheimer's Disease." The press release contained statements from Defendants Barbier and Kupiec and stated, in relevant part:

> **- Two Upcoming Phase 3 Studies and a Previously Completed Phase 2 Program Support a New Drug Application Filing for Simufilam in Alzheimer's disease –**
>
> **- Agreement Reached to Use ADAS-Cog as Co-Primary Efficacy Endpoint –**
>
> **- Pivotal Phase 3 Program Remains On-track to be Initiated 2nd Half 2021 –**
>
> . . . Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company developing product candidates for Alzheimer's disease, ***today announced the successful completion of an End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) for simufilam***, its lead drug candidate for the treatment of Alzheimer's disease. ***Official EOP2 meeting minutes indicate FDA and Cassava Sciences agree on key elements of a pivotal Phase 3 clinical program in support of a New Drug Application (NDA) filing for simufilam*** in Alzheimer's disease. Agreements reached during the EOP2 meeting show a clear path forward for advancing simufilam into Phase 3 studies in the second half of 2021.
>
> "***For over 10 years we've been doing basic research and early drug development with simufilam," said Remi Barbier***, President & CEO. "We are excited to finally advance simufilam into pivotal Phase 3 clinical studies in people with Alzheimer's disease. ***We believe the underlying science is solid, the drug appears safe and the clinical roadmap makes sense.*** We've crossed the Rubicon."
>
> ***"We appreciate the valuable guidance and flexibility FDA has provided," added Jim Kupiec, MD, Cassava Sciences' Chief Clinical Development Officer. "We look forward to continuing a collaborative dialogue throughout the pivotal Phase 3 clinical development program."***

> Simufilam is a novel drug, discovered at Cassava Sciences, that targets both neuroinflammation and neurodegeneration. ***The EOP2 meeting discussion was supported by years of scientific and clinical data, including positive results from a previously completed Phase 2 clinical program with simufilam in Alzheimer's disease. In a double-blind, randomized, placebo-controlled Phase 2b study, simufilam demonstrated robust effects on primary and secondary outcome measures, with no safety issues. Recently, the Company announced that simufilam improved cognition in subjects with Alzheimer's disease in a 6-month interim analysis of an open-label study, with no safety issues.***
>
> The EOP2 meeting took place mid-January. FDA attendees included Robert Temple, MD, Deputy Center Director for Clinical Science and Senior Advisor in the Office of New Drugs; Billy Dunn, MD, Director, Office of Neuroscience; Eric Bastings, MD, Director, Division of Neurology, and others.
>
> Official meeting minutes confirm that Cassava Sciences and FDA are aligned on key elements of a Phase 3 clinical program for simufilam. ***FDA has agreed that the completed Phase 2 program, together with an upcoming and well-defined Phase 3 clinical program, are sufficient to show evidence of clinical efficacy for simufilam in Alzheimer's disease.*** There is also agreement that the use of separate clinical scales to assess cognition (ADAS-cog1) and function (ADCS-ADL2) are appropriate co-primary endpoints of efficacy. A clinical scale that combines cognition and function, such as iADRS3, is a secondary efficacy endpoint.

(Italicized emphasis added.)

242. The statements made in ¶ 241 were false and misleading because they failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker

test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

March 9, 2021 Press Release Presentation at H.C. Wainwright Annual Global Life Sciences Virtual

243. On March 9, 2021, the Company announced that it "ha[d] entered into a drug supply agreement with Evonik Industries AG for simufilam. Under the agreement, Evonik will supply Cassava Sciences with large-scale, clinical-grade quantities of simufilam, a drug candidate for the treatment of Alzheimer's disease."

244. Also on March 9, 2021, the Company presented at the H.C. Wainwright Annual Global Life Sciences Conferences. During his presentation, Barbier stated:

> I think, the key take-home message for around Cassava Sciences is that simufilam is a Phase 3 ready asset in 2021. There are many, many drivers of our clinical development plan, ***but suffice to say that it is our scientific plan and our clinical plan is based on years and years of research around basic biology and specifically the basic biology of filamin A,*** a protein we'll talk more about.

(Emphasis added.)

245. Barbier furthered that "[u]nlike many drugs, simufilam has a dual mechanism of action, meaning that it – it is intended to both reduce neurodegeneration as well as reduce neuroinflammation. ***And we have a lot of published data and around both the preclinical data the clinical data and mechanism of action for simufilam.***" (Emphasis added.)

246. Additionally, Defendant Barbier represented that the mechanism of simufilam that makes the medication work has been "well described and published," stating:

> One of our contribution [*sic*] to the field, to the Alzheimer's field is that the Alzheimer's brain in fact carries an altered form of filamin A. And what we are saying is that, it is the altered form, the altered filamin A protein that is critical to the toxicity of amyloid beta. ***How that happens again rather complicated, there's a very specific and well described and published mechanism of action, but the take home message here is that simufilam binds the altered form of filament A, restores its proper shape and function and disables amyloid beta from signaling via all these different receptors, hence reducing neurodegeneration and neuroinflammation***.

(Emphasis added.)

247. Barber concluded his presentation, stating:

> So in conclusion to [sic] ***Phase 2b study shows that simufilam did improve an entire panel of biomarkers of disease pathology, inflammation and blood-brain barrier integrity and at the Phase 2b data do replicate prior clinical results, and more importantly, are consistent with the science, consistent with the mechanism of action studies***.

(Emphasis added.)

248. On March 23, 2021, the Company issued a press release touting its "Full-year 2020 Financial Results and Business Highlights." The press release contained the following statements from Defendants Barbier and Schoen, in relevant part:

> "In Q1 2021 we announced that our lead drug candidate, simufilam, improved cognition scores in 50 patients with Alzheimer's disease who completed at least 6 months of open-label treatment," ***said Remi Barbier***, President & CEO. "In mid-2021, we look forward to announcing cognition scores in patients who'll have completed at least 12 months of open-label treatment with simufilam. To our knowledge, no drug has stabilized, much less improved, cognition scores over 12 months in patients with Alzheimer's disease. For this reason, I feel there is a sense of anticipation around the upcoming release of 12-month clinical data from our open-label study, as well as our plans to conduct a pivotal Phase 3 program with simufilam in the second half of 2021. ***With solid science, the right people in place, cash in the bank and a clinical roadmap that makes sense, I think Cassava Sciences is positioned to becoming a premier organization to serve patients with Alzheimer's disease."***
>
> "We have approximately $280 million in cash on our balance sheet, against expected cash use of approximately $20 to $25 million in 2021," said Eric Schoen, Chief Financial Officer. "We believe our cash levels support a pivotal Phase 3 clinical program of simufilam in Alzheimer's disease."

(Emphasis added.)

249. The statements made in ¶¶ 243-248 were false and misleading because they failed to disclose that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

March 23, 2021 Form 10-K

250. Also on March 23, 2021, Cassava filed its annual report for the 2020 Fiscal Year on Form 10-K with the SEC (the "2020 10-K"). The 2020 10-K, signed by Dr. Friedmann and Defendants Barbier, Schoen, Gussin, O'Donnell, Robertson, and Scannon, contained certifications, signed by Defendants Barbier and Schoen, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Exchange Act and the Sarbanes-Oxley Act of 2002 ("SOX") attesting to the accuracy of the financial statements contained in the 2020 10-K, the disclosure of any

material changes to the Company's internal controls, and the disclosure of any fraud committed by the Company, its officers, or its directors.

251. The 2020 10-K represented the following about simufilam:

> Our lead therapeutic product candidate, simufilam, is a proprietary small molecule (oral) drug. Simufilam targets an altered form of a protein called filamin A (FLNA) in the Alzheimer's brain. ***Published studies have demonstrated that the altered form of FLNA causes neuronal dysfunction, neuronal degeneration and neuroinflammation.***
>
> We believe simufilam improves brain health by reverting altered FLNA back to its native, healthy conformation, thus countering the downstream toxic effects of altered FLNA. ***We have generated and published experimental and clinical evidence of improved brain health with simufilam.*** Importantly, simufilam is not dependent on clearing amyloid from the brain. Since simufilam has a unique mechanism of action, we believe its potential therapeutic effects may be additive or synergistic with that of other therapeutic candidates aiming to treat neurodegeneration.
>
> ***Simufilam has demonstrated a multitude of beneficial effects in animal models of disease, including normalizing neurotransmission, decreasing neuroinflammation, suppressing neurodegeneration, and restoring memory and cognition.***
>
> ***In 2019, we completed a small, first-in-patient, clinical-proof-of-concept, open-label Phase 2a study of simufilam in the U.S.,*** with substantial support from the *National Institute on Aging* (NIA), a division of the NIH. ***Treatment with simufilam for 28 days significantly improved key biomarkers of Alzheimer's pathology, neurodegeneration and neuroinflammation ($p<0.001$). Biomarkers effects were seen in all patients in both cerebrospinal fluid (CSF) and plasma.***
>
> In September 2020, we announced final results of a **Phase 2b study** with simufilam in Alzheimer's disease. ***In this clinical study funded by the NIH, Alzheimer's patients treated with 50 mg or 100 mg of simufilam twice-daily for 28 days showed statistically significant ($p<0.05$) improvements in CSF biomarkers of disease pathology, neurodegeneration and neuroinflammation, versus Alzheimer's patients who took placebo. In addition, Alzheimer's patients treated with simufilam showed improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo (Effect Size 17-46%).*** Cognitive improvements correlated most strongly (R^2=0.5) with decreases in levels of P-tau181.

(Emphasis added.)

252. The 2020 10-K, in a section titled "Our Scientific Approach is Different," represented the following about Cassava's research:

> Using scientific insight and advanced techniques in molecular biochemistry, bioinformatics and imaging, we have elucidated this protein dysfunction. ***Through this work, we have produced experimental evidence that altered FLNA plays a critical role in Alzheimer's disease.*** We engineered a family of high-affinity, small molecules to target this structurally altered protein and restore its normal shape and function. This family of small molecules, including our lead therapeutic candidate, simufilam, was designed in-house and characterized by our academic collaborators.
>
> * * *
>
> FLNA is a scaffolding protein widely found throughout the body. A healthy scaffolding protein brings multiple proteins together, initiating their interaction. However, an altered form of FLNA protein is found in the Alzheimer's brain. ***Our experimental evidence shows that altered FLNA protein contribute to Alzheimer's disease by disrupting the normal function of neurons, leading to neurodegeneration and brain inflammation.*** Our product candidate, simufilam, aims to counter the altered and toxic form of FLNA in the brain, thus restoring the normal function of this critical protein. Our novel science is based on stabilizing – but not removing – a critical protein in the brain.
>
> * * *
>
> ***Our science is published in multiple peer-reviewed journals. In addition, our research has been supported by NIH under multiple research grant awards. Each grant was awarded following an in-depth, peer-reviewed evaluation of our approach for scientific and technical merit by a panel of outside experts in the field.*** Strong, long-term support from NIH has allowed us to advance our two product candidates for neurodegeneration, simufilam and SavaDx, into clinical development.

(Emphasis added.)

253. The 2020 10-K stated the following in a section titled "Simufilam is our Proprietary Drug for the Treatment of Alzheimer's Disease":

> ***We have generated and published experimental evidence of improved brain health by restoring altered FLNA with simufilam, our lead therapeutic product candidate.*** Simufilam is a proprietary small molecule drug that represents an entirely new scientific approach to treat neurodegeneration. ***Published studies have demonstrated that simufilam targets an altered form of a protein called FLNA that is pervasive in the Alzheimer's brain.*** Altered FLNA causes neuronal dysfunction, neuronal degeneration and neuroinflammation. We believe our drug candidate, simufilam, improves brain health by reverting altered FLNA back to its native, healthy conformation, thus countering downstream toxic effects of altered FLNA. Importantly, simufilam is not dependent on clearing amyloid from the

brain. The following is a summary profile of simufilam's drug development program.

Over the past ten years, we successfully conducted basic research, in vitro studies and preclinical studies in support of an Investigational New Drug (IND) submission to FDA for simufilam, including requisite studies around safety pharmacology, toxicology, genotoxicity and bioanalytical methods. In 2017 we filed an IND with FDA for simufilam.

* * *

Given the absence of any observable dose-limiting effects in healthy adults in a Phase 1 study, ***a strong scientific rationale, and multiple peer-reviewed publications and research grant awards, we believe this program demonstrated favorable proof-of-principle for the development of simufilam in Alzheimer's disease.***

(Emphasis added.)

254. Regarding the results of the Phase 2a Clinical Study, the 2020 10-K stated the following:

A key objective of our Phase 2a study was to measure levels of CSF biomarkers in the brain. Key results of this study include (**Figure 1**):

- Total tau (T-tau) decreased 20% ($p<0.001$)
- ***Phosphorylated tau (P-tau) decreased 34% ($p<0.0001$)***
- Neurofilament light chain (NfL), a marker for neurodegeneration, decreased 20% ($p<0.0001$)
- Neurogranin, a marker for cognitive decline, decreased 32% ($p<0.001$)
- Neuroinflammatory marker YKL-40, an indicator of microglial activation, decreased 9% ($p<0.0001$)
- Proinflammatory Interleukin 6 (IL-6) decreased 14% ($p<0.0001$)
- ***Proinflammatory Interleukin 1 beta (IL-1β) decreased 5% ($p<0.0001$)***
- ***Proinflammatory Tumor Necrosis Factor alpha (TNFα) decreased 5% ($p<0.001$)***
- The ratio of CSF P-tau to $A\beta_{42}$, a widely accepted biochemical value of Alzheimer's disease, improved in all patients ($p<0.001$)

* * *

Consistent with over 10 years of basic research and pre-clinical data, we believe our Phase 2a study showed clinical evidence of simufilam's mechanism of action and drug-target engagement, including:

- ***Improvements in biomarkers of Alzheimer's disease in CSF, plasma and lymphocytes;***
- ***Consistency across biomarker improvements in CSF, plasma, and lymphocytes;***

- Significant reductions ($p<0.01$) in both nitrated and phosphorylated forms of tau protein;
- Evidence that each individual patient showed biomarker responses to simufilam;
- Evidence that simufilam reversed the shape of altered filamin A in lymphocytes;
- Evidence that simufilam reduced levels of amyloid bound to alpha 7 in nicotinic receptors in lymphocytes;
- Early clinical validation of the drug target–altered filamin A– as a facilitator protein between amyloid beta and both neuroinflammation and tau pathology.

* * *

In February 2020, our Phase 2a study was published in *The Journal of Prevention of Alzheimer's Disease* (JPAD), a technical journal for the research community. ***This peer-reviewed publication highlighted that biomarkers of Alzheimer's disease pathology (P-tau, total tau and $A\beta_{42}$), neurodegeneration (NfL and neurogranin) and neuroinflammation (YKL-40, IL-6, IL-1β and TNFα) improved significantly after 28 days of treatment with simufilam.***

(Emphasis added.)

255. Regarding why the Company disregarded the poor May 2020 results, but accepted the positive September 2020 results of the Phase 2b clinical study, the Form 10-K stated the following:

> In May 2020, we announced that an outside lab with whom we had no prior work experience had generated an initial bioanalysis of CSF samples from our Phase 2b study. The data set from the initial bioanalysis showed unnaturally high variability and other problems, such as no correlation among changes in levels of biomarkers over 28 days, even in the placebo group, and different biomarkers of disease moving in opposite directions in the same patient. Importantly, we later observed no statistical correlation between levels of simufilam in plasma and CSF, further indicating an invalid analysis. ***Overall, we believe data from the initial bioanalysis can be interpreted as anomalous and highly improbable. With its validity in question, the initial bioanalysis serves no useful purpose. Backup CSF samples were subsequently sent to a second outside lab for bioanalysis.*** All bioanalyses were conducted under blinded conditions to eliminate any possibility of bias.
>
> On September 14, 2020, we reported final positive Phase 2b clinical study results. Drug was safe and well-tolerated in this study. ***Simufilam significantly ($P<0.05$) improved an entire panel of validated biomarkers of***

> ***disease in patients with Alzheimer's disease compared to a placebo group. In addition, Alzheimer's patients treated with simufilam showed directional improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo*** (Effect Sizes 46-17%). Cognitive improvements correlated most strongly (R^2=0.5) with decreases in levels of P-tau181 in CSF. The study achieved a 98% response rate, defined as the proportion of study participants taking simufilam who showed improvements in biomarkers. We later observed a direct correlation between levels of simufilam in plasma and CSF, which provides strong evidence of a valid analysis. ***Importantly, we believe these data are consistent with prior clinical and preclinical results, the drug's mechanism of action and over 10 years of basic research.***

(Emphasis added.)

256. The 2020 10-K represented the following about the Phase 2b results:

> ***Key biomarker results include the following*** (all p-values versus placebo) (**Figure 3):**
>
> - Proinflammatory IL-6 (Interleukin 6) is produced in response to tissue stress and injury.
> - ***IL-6 decreased 10% (p<0.01) for patients in the 50 mg drug group.***
> - ***IL-6 decreased 11% (p<0.01 in the 100 mg drug group.***
>
> * * *
>
> - sTREM2 is a neuroinflammation biomarker that has commanded substantial recent attention from researchers for its role in Alzheimer's disease and frontotemporal dementia.
> - ***sTREM2 decreased 43% (p<0.01) for patients in the 50 mg drug group.***
> - ***sTREM2 decreased 46% (P<0.01) for patients in the 100 mg drug group***.
>
> - ***Simufilam improved the Albumin Ratio, a Test of Blood-brain Barrier (BBB) Permeability….***

(Emphasis added.)

257. The 2020 10-K also made the same representations regarding "spatial memory" improvements as stated in ¶¶ 206, 223, and 236.

258. The 2020 10-K also contained this general risk warning:

> ***Since 2017, we have concentrated a substantial portion of our research and development efforts on the treatment and detection of Alzheimer's disease, an area of research that has seen significant failure rates. Further, our product candidates are based on new scientific approaches and novel technology, which***

makes it difficult to predict the time and cost of product candidate development and likelihood of success.

Since 2017, we have concentrated a substantial portion of our research and development efforts on experimental methods for the treatment and detection of Alzheimer's disease. Prior efforts by biopharmaceutical companies to develop new treatments for Alzheimer's disease have seen very limited clinical success. No new treatments have been approved for Alzheimer's disease since 2003, and since that time, while many large clinical studies have been completed, no drug candidate has shown clear evidence of clinical efficacy in large, Phase 3 clinical studies. FDA-approved drugs for Alzheimer's disease only address symptoms, and there are no FDA-approved disease modifying therapeutics available for patients with Alzheimer's disease. Notwithstanding these substantial challenges to date, we seek to improve brain health by addressing the neurodegeneration and neuroinflammation components of Alzheimer's disease. Our lead drug candidate for Alzheimer's disease is based on a new approach of stabilizing – but not removing – a critical protein in the brain. We cannot be certain that our novel technologies will lead to an approvable or marketable product. In addition, because FDA has limited comparators to evaluate our lead drug candidate, we could experience a longer than expected regulatory review process and increased development costs.

(Emphasis in original.)

259. Moreover, the 2020 10-K contained this general risk warning:

Our clinical studies may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization.

* * *

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical studies, and results of early clinical studies of our product candidates may not be predictive of the results of later-stage clinical studies. The results of clinical studies in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical studies of the same product candidate due to numerous factors, including changes in study procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen, and other clinical study protocols and the rate of dropout among clinical study participants. Open-label extension studies may also extend the timing and cost of a clinical study substantially. Product candidates in later stages of clinical studies

> may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical studies. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier studies. This is particularly true in neurodegenerative diseases, where failure rates historically have been higher than in many other disease areas. Most product candidates that begin clinical studies are never approved by regulatory authorities for commercialization.
>
> * * *
>
> In addition, even if such clinical studies are successfully completed, we cannot guarantee that FDA or foreign regulatory authorities will interpret the results as we do, and more studies could be required before we submit our product candidates for approval. To the extent that the results of the studies are not satisfactory to FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional studies in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidates, which may also limit its commercial potential.

(Emphasis added.)

260. Finally, the 2020 10-K contained this statement regarding the Company's internal controls:

> *Evaluation of disclosure controls and procedures.*
>
> Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. ***Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission, or SEC, rules and forms and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.***
>
> *Management's annual report on internal control over financial reporting.* Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Our management has assessed the effectiveness of internal control over financial reporting as of December 31, 2020.

Our assessment was based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework (2013 Framework).

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on the COSO criteria, we believe our internal control over financial reporting as of December 31, 2020 was effective.

* * *

Changes in internal control over financial reporting.

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

(Bolded emphasis added.)

261. Despite the generalized risk warnings concerning new drug research and clinical trials, the 2020 10-K failed to disclose or discuss the specific risks the Company was facing due

to its use of overstated and manipulated clinical trial data. Thus, the statements in ¶¶ 251-260 were false and misleading and failed to disclose that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

March 31, 2021 Proxy Statement

262. On March 31, 2021, Cassava filed the 2021 Proxy Statement with the SEC. Dr. Friedmann and Defendants Barbier, Gussin, O'Donnell, Robertson, and Scannon solicited the 2021 Proxy Statement filed pursuant to Section 14(a) of the Exchange Act, which contained material misstatements and omissions.[12]

[12] Plaintiff' allegations with respect to the misleading statements in the 2021 Proxy Statement are based solely on negligence; they are not based on any allegation of reckless or knowing conduct by or on behalf of the Individual Defendants, and they do not allege, and do not sound in, fraud.

263. The 2021 Proxy Statement called for Company shareholders to, *inter alia*: (1) reelect Defendants Barbier, Robertson, and Scannon to the Board; (2) approve an amendment to the Company's 2018 Omnibus Incentive Plan (the "2018 Plan") to add an additional 4 million shares to the 2018 Plan for issuance to Company employees, directors, and consultants; (3) ratify Ernst & Young LLP as the Company's independent auditor for the fiscal year ending December 31, 2021; and (4) approve, by a nonbinding advisory vote, the 2020 executive compensation for Dr. Friedmann and Defendants Barbier and Schoen.

264. The 2021 Proxy Statement stated the following regarding the Board's risk oversight functions:

> The Board of Directors maintains a structure with the Chief Executive Officer of the Company holding the position as Chairman of the Board of Directors, and with an Audit Committee and Compensation Committee for oversight of specific areas of responsibility, discussed further below. The Company does not have a lead independent director. ***The Company believes that this structure is appropriate and allows for efficient and effective oversight***, given the Company's relatively small size (both in terms of number of employees and in scope of operational activities directly conducted by the Company), its corporate strategy (including the use of outsourcing for certain activities) and its focus on drug and diagnostic research and development. ***The Chairman, President and Chief Executive Officer, the Committees of the Board of Directors and, as needed, other executive officers and employees of the Company provide the Board of Directors with information regarding the Company's risks. The Board of Directors, or the Committee with special responsibility for oversight of the area implicated by the highlighted risks, then uses this information to perform its oversight role and inform its decision making with respect to such areas of risk.***

(Emphasis added.)

265. The 2021 Proxy Statement contained the following description of the Board committees:

> ***The Board of Directors has a standing Audit Committee that oversees the Company's accounting and financial reporting processes and audits of the***

Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to these allegations and related claims.

> ***Company's financial statements.*** The Company also has a standing Compensation Committee. The Board of Directors does not have a lead director or a standing Nominating Committee. Mr. Barbier is the Chairman of the Board of Directors, President and Chief Executive Officer of the Company.
>
> The Audit Committee consists of directors Dr. Gussin, Mr. Robertson and Dr. Scannon. . .. The Board of Directors of the Company has determined that these individuals are independent as defined under the Nasdaq Stock Market LLC listing standards as well as the SEC rules. The Board of Directors has also determined that Mr. Robertson is an "audit committee financial expert" as defined in the SEC rules. The Audit Committee operates under a written charter adopted by the Board of Directors. The Company maintains a copy of the Audit Committee charter on its website: www.cassavasciences.com. The Audit Committee reviews the Company's internal accounting procedures, consults with and reviews the services provided by the Company's independent registered public accounting firm and makes recommendations to the Board of Directors regarding the selection of the independent registered public accounting firm. The Audit Committee held four meetings during fiscal year 2020.
>
> The Compensation Committee consists of directors Dr. Gussin and Mr. Robertson. The Board of Directors of the Company has determined that these individuals are independent as defined under the Nasdaq Stock Market LLC listing standards. ***The Compensation Committee reviews and recommends to the Board of Directors the salaries, incentive compensation and benefits of the Company's officers and administers the Company's stock plans and employee benefit plans.*** Refer to the section entitled "Compensation Discussion and Analysis" for more information about the Company's Compensation Committee and its processes and procedures. The Compensation Committee operates under a written charter adopted by the Board of Directors. The Company maintains a copy of the Compensation Committee charter on its website: www.cassavasciences.com. The Compensation Committee held three meetings during fiscal year 2020.

(Emphasis added.)

266. The 2021 Proxy Statement also listed certain responsibilities of the Audit Committee, that included, "[a]ssist[ing] the Board of Directors of the Company in oversight and monitoring" and overseeing "the adequacy and effectiveness of the Company's systems of internal accounting and financial controls[.]"

267. The 2021 Proxy Statement noted that of "the 1,000,000 shares of Common Stock originally authorized under the 2018 Plan, after all award grants made by the Compensation

Committee of our Board of Directors (the "Compensation Committee"), 242,188 shares remained available for grant as of March 16, 2021."

268. The 2021 Proxy Statement was materially misleading because it failed to disclose that: (1) contrary to the 2021 Proxy Statement's descriptions of the Board's risk oversight function and the Audit Committee's responsibilities, the Board and its committees were not adequately exercising these functions, were causing or permitting the Company to submit manipulated data to the FDA and to issue false and misleading statements to the investing public, and thus the Individual Defendants on the Board were breaching their fiduciary duties; and (2) the Individual Defendants on the Board who were breaching their fiduciary duties were improperly interested in increasing their unjust compensation by seeking shareholder approval of the amendment to the 2018 Plan, which the Individual Defendants serving on the Compensation Committee were improperly administering by rewarding misconduct.

269. The 2021 Proxy Statement also failed to disclose that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its

presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

270. As a result of the material misstatements and omissions contained in the 2021 Proxy Statement, Company shareholders reelected Defendants Barbier, Robertson, and Scannon to the Board, allowing them to continue breaching their fiduciary duties to Cassava; ratified Ernst & Young LLP as independent auditor, and approved, on a nonbinding advisory basis, the 2020 compensation Dr. Friedman and Defendants Barbier and Schoen. Company shareholders did not approve the amendment to the 2018 Plan.

April 21, 2021 Press Release

271. On April 21, 2021, Cassava issued a press release announcing its results for the fiscal quarter ended March 31, 2021. The press release contained a statement from Defendant Barbier and stated in relevant part:

> **- 9 Month Interim Analysis of Open-label Study to be Presented at a Major Scientific Conference in July 2021 as an Oral Presentation –**
>
> **- Initiation of Pivotal Phase 3 Program Remains On-track for 2nd Half 2021 –**
>
> **- Initiation of Cognition Maintenance Study On-track for June 2021 –**
>
> **- Cash and cash equivalents were $282.2 million at March 31, 2021 –**
>
> . . . Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced financial results for the first quarter ended March 31, 2021 and guidance regarding the release of new clinical data with simufilam. Simufilam is the Company's lead drug candidate to treat Alzheimer's disease.
>
> ***"Alzheimer's is a progressive disease, so a patient's cognition is expected to worsen over time," said Remi Barbier, President & CEO. "Patients' cognition scores actually improved following 6 months of open-label treatment with***

simufilam. Showing similar drug effects following 9 months of open-label treatment would be remarkable, yet consistent with simufilam's mechanism of action. Eventually, we'd like this drug candidate to benefit cognition for a year or longer."

In July 2021, Cassava Sciences plans to announce results of a pre-specified interim analysis that summarizes safety and cognition data on approximately the first 50 subjects to complete at least 9 months of open-label drug treatment. The Company will present these data July 26 - 29th at the 2021 Alzheimer's Association International Conference (AAIC). AAIC's scientific committee has invited the Company's scientists to present the dataset as an oral presentation.

About the Open-label Study with Simufilam

In March 2020, Cassava Sciences initiated a long-term, open-label study to evaluate simufilam in patients with Alzheimer's disease. This study is funded by a research grant award from the National Institutes of Health (NIH). The open-label study is intended to monitor the long-term safety and tolerability of simufilam 100 mg twice-daily for 12 months or longer in patients with Alzheimer's disease. Another study objective is to measure changes in cognition on ADAS-Cog, a standard test of cognition in Alzheimer's disease. The study's clinical protocol has pre-specified cognition measurements at 6, 9 and 12 months.

The study's target enrollment is approximately 150 subjects with mild-to-moderate Alzheimer's disease (recently increased by 50 subjects). One-hundred subjects have enrolled in this study across multiple clinical sites in the U.S. and Canada.

On February 2, 2021, Cassava Sciences announced positive results of a first interim analysis that summarizes clinical data on the first 50 subjects to complete 6 months of open-label treatment. Patients' cognition scores improved from baseline following 6 months of simufilam treatment, with no safety issues. Six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6.

In September 2021, Cassava Sciences plans to announce results of an interim analysis that summarizes safety and cognition data on approximately the first 50 subjects to complete at least 12 months of open-label drug treatment.

About the Cognition Maintenance Study (CMS)

In June 2021, Cassava Sciences plans to initiate a double-blind, randomized, placebo-controlled study in patients with Alzheimer's disease. Patients who have completed at least one year of open-label treatment with simufilam qualify to enroll in the *Cognition Maintenance Study* (CMS). Study subjects in the CMS will be randomized (1:1) to simufilam or placebo for six months. The CMS is designed to

> compare simufilam's effects on cognition in Alzheimer's patients who continue with drug treatment versus patients who discontinue drug treatment.

(Italicized emphasis added.)

272. The April 21, 2021 press release was false and misleading and failed to disclose that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

April 28, 2021 B. Riley Neuroscience Conference

273. On April 28, 2021, Defendant Barbier presented at the B. Riley Neuroscience Conference. During his presentation he stated:

> ***And that is why, when we look at our Phase 2 results -- Phase 2b. And you look at our Phase 2 results. Phase 2b – they both Phase 2a, Phase 2b, what we see that has never been seen for is a massive reduction in biomarkers of neuroinflammation, biomarkers of neurodegeneration and other indications of disease***.

(Emphasis added.)

274. Later, Defendant Barbier boasted about the "consistency" of data received through pre-clinical and clinical studies, stating:

> But again, connecting the dots from an academic thesis to a drug that works for the average patient. I haven't seen that too often. ***Hear what we really like, one of the things we like about the program. And perhaps really where we get our confidence in the Phase 3 possibilities. Is that all the dots connect. Again, all the way from basic biology to CSF markers to mechanism of actions, animals and now cognition***.

(Emphasis added.)

275. The statements in paragraphs ¶¶ 273-274 were false and misleading because they failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls.

As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

June 21, 2021 Press Release

276. On June 21, 2021, the Company issued a press release providing a "Mid-Year Corporate Update[.]" The press release contained a statement from Defendant Barbier and stated, in relevant part:

- **Open-label Study Completes Patient Enrollment**
- **Cognition Maintenance Study Initiated May 2020, now 30% Enrolled**
- **6-month Biomarker Data to be Presented at AAIC Conference in July**
- **9-month Safety & Cognition Data to be Presented at AAIC Conference**
- **Clinical Results with SavaDx to be Presented at AAIC Conference**
- **Phase 3 Program Initiation Remains On-track for 2nd Half 2021**

> . . .Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer's disease, today announced a mid-year update that highlights clinical development progress and provides guidance on upcoming data releases for simufilam and SavaDx. Simufilam is Cassava Sciences' lead drug candidate to treat Alzheimer's disease; SavaDx is an investigational diagnostic candidate to detect Alzheimer's with a simple blood test.
>
> ***"Patients with Alzheimer's want clear and present evidence of drug efficacy," said Remi Barbier, President & CEO. "The recent regulatory approval of a new drug for Alzheimer's was a bit of a donnybrook over this very topic. Our clinical strategy with simufilam is to show real-world safety and efficacy by conducting both, randomized controlled trials, and an on-going open-label study. Ideally, biomarker and cognition data from our studies converge and result in health benefits for patients."***
>
> Clinical progress across Cassava Sciences' product portfolio is summarized below.
>
> **Update on Open-label Study with Simufilam**
>
> * * *
>
> The open-label study has completed its target enrollment of 150 subjects. By physician and patient request, clinical sites may continue to enroll additional

subjects up through the initiation of the Company's Phase 3 pivotal program of simufilam.

Guidance on Clinical Data Release

Cassava Sciences plans to announce results of an interim analysis on safety and cognition for the first 50 subjects to complete 9 months of open-label drug treatment. These cognition data will be presented at the 2021 Alzheimer's Association International Conference (AAIC) in Denver, CO, the week of July 26-30th. The scientific committee of AAIC has invited the Company's scientists to present these data as an oral presentation.

Cassava Sciences will also present at AAIC biomarker data from the open-label study, including:

- Biomarkers of Alzheimer's disease: amyloid beta42, total tau, P-tau181.
- Biomarkers of neurodegeneration: neurogranin, neurofilament light chain (NfL).
- Biomarkers of neuroinflammation: YKL-40, sTREM2 and HMGB1.

Biomarker data were analyzed from cerebrospinal fluid (CSF) collected from twenty-five study subjects who underwent a small volume lumbar puncture at baseline and again after completing 6 months of open-label drug treatment.

* * *

Update on the Phase 3 Clinical Program

Cassava Sciences plans to initiate a Phase 3 program of simufilam in Alzheimer's disease in the second half of 2021. A clinical research organization (CRO) has been selected and will be publicly announced shortly. Large-scale, cGMP drug production capabilities are in-place to support the Phase 3 clinical program.

(Italicized emphasis added; some original emphasis removed.)

277. The June 21, 2021 press release it failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b

results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

June 22, 2021 Raymond James Human Health Innovation Conference

278. On June 22, 2021, Defendant Barbier presented at the Raymond James Human Health Innovation Conference. During his presentation, he stated:

> ***The preclinical data and the mechanism of action studies in support of simufilam are published in a number of peer-reviewed publications. And we think that these publications and certainly our clinical data point to simufilam's potential as a drug-modifying drug – disease-modifying drug, pardon me, for Alzheimer's that also provides symptomatic improvement.***

(Emphasis added.)

279. Later in the presentation, Defendant Barbier emphasized the consistency of the Company's clinical results, stating:

> At this point, we can say that simufilam appeared to enhance cognition, and that those enhancements in fact correlate at some level with P-tau181. ***But at a very high strategic level, what we show here is that the Phase 2b data replicate earlier clinical results and are consistent with mechanism of action studies and published preclinical data***.

(Emphasis added.)

280. Defendant Barbier's statements at the conference in ¶¶ 278-279 were false and misleading because they failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

July 26, 2021 Press Releases

281. On July 26, 2021, Cassava issued a press release titled "Cassava Sciences Announces Positive Data with SavaDx from a Randomized Controlled Phase 2b Study of Simufilam[.]" The press release, which included a statement from Defendant Barbier, stated:

- **SavaDx Detected Significant Changes in Plasma Levels of Altered Filamin A in Patients with Alzheimer's Disease Before and After Simufilam Treatment**

- **Simufilam 100 mg and 50 mg Reduced Plasma Levels of Altered Filamin A in Alzheimer's Patients 48% (p=0.003) and 44% (p=0.02) Respectively**

- **Plasma Results with SavaDx Track Plasma Results with p-Tau181**

- **Plasma Data Provide Evidence of Target Engagement**

- **Poster Presentation at AAIC Today**

> . . . Cassava Sciences, Inc. (Nasdaq: SAVA***) today announced positive clinical data with SavaDx, an investigational diagnostic/biomarker to detect Alzheimer's disease with a simple blood test. SavaDx was used to measure plasma levels of altered filamin A before and after simufilam treatment in patients with Alzheimer's disease.*** In this Phase 2b randomized, controlled trial sponsored by the National Institutes of Health (NIH), simufilam significantly reduced plasma levels of altered filamin A in Alzheimer's patients treated for 28 days. ***Plasma levels of p-tau181 also dropped significantly in these same patients.***
>
> Simufilam 100 mg and 50 mg reduced plasma levels of altered filamin A by 48% (p=0.003) and 44% (p=0.02) respectively, versus placebo. Additionally, ***simufilam 100 mg and 50 mg reduced plasma levels of p-tau181 by 17% (p=0.01) and 15% (p=0.02) respectively, versus placebo.*** Plasma p-tau181 is a biomarker that is known to be elevated in Alzheimer's disease.
>
> ***"We believe altered filamin A is a major culprit in Alzheimer's disease," said Remi Barbier, President & CEO. "Before simufilam treatment, SavaDx detected high plasma levels of altered filamin A in patients. After simufilam treatment, levels dropped significantly. We believe these data provide clear evidence that simufilam binds to and engages its intended target to produce treatment effects."***
>
> Treatment effects on CSF biomarkers for this Phase 2b study have been previously reported.

(Italicized emphasis added.)

282. Additionally, the press release referenced a "poster presentation titled, 'SavaDx, a Novel Plasma Biomarker to Detect Alzheimer's Disease, Confirms Mechanism of Action of Simufilam.'" The poster included the names of Drs. Burns and Wang. Likewise, the poster listed Zhe Pei from CUNY, Qiang Xu from Abilene Christian University, Lynn Brunelle from Quanterix, and George Thorton from Cassava.

283. The statements in ¶¶ 281-282 were false and misleading because they failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

284. Additionally, the statement in ¶ 281 was false and misleading because it failed to disclose that (i) the biomarker results the Company utilized for plasma P-tau181 errantly excluded data, which if included would have resulted in a non-statistically significant change and (ii) the poster that Cassava referenced in the press release and presented at the AAIC contained falsified and/or manipulated "altered Filamin A" data that were materially different from Western blot data obtained from a FOIL request.

July 29, 2021 Press Release

285. On July 29, 2021, Cassava issued a press release, one of two released that day, titled, "Cassava Sciences Announces Positive Biomarker Data with Simufilam in Alzheimer's Disease[.]" The press release contained a statement from Defendant Barbier, and stated in relevant part:

- **Simufilam Significantly Improved Biomarkers in Alzheimer's Patients Treated for 6 Months**
- **Robust Improvements Seen in All Measured Biomarkers of Disease, Neurodegeneration and Neuroinflammation (p< 0.00001)**
- **Biomarker Improvements Track with Cognitive Improvements**

- **Oral Presentation at AAIC Today**

> . . . Cassava Sciences, Inc. (Nasdaq: SAVA) ***today announced positive biomarker data from an open-label study of simufilam,*** the Company's investigational drug for the treatment of Alzheimer's disease.
>
> ***In a clinical study funded by the National Institutes of Health (NIH), simufilam significantly improved all measured biomarkers in patients with Alzheimer's disease following 6 months of open-label treatment. Biomarkers are objective biological data. There are no placebo effects.***
>
> Cerebrospinal fluid (CSF) biomarkers of disease pathology, t-tau and p-tau181, decreased 38% and 18%, respectively (both p<0.00001). CSF biomarkers of neurodegeneration, neurogranin and Nfl, decreased 72% and 55%, respectively (both p<0.00001). CSF biomarkers of neuroinflammation, sTREM2 and YKL-40, decreased 65% and 44% (both p<0.00001). CSF biomarker data were collected from 25 patients with mild-to-moderate Alzheimer's disease who completed 6 months of simufilam treatment in an on-going open-label study.
>
> ***"Six months of simufilam treatment robustly improved brain biomarkers," said Remi Barbier, President & CEO. "In this same study simufilam also improved cognition. These data suggest simufilam has potential to provide durable treatment effects for people living with Alzheimer's."***

(Italicized emphasis added.)

286. The statements in ¶ 285 were false and misleading because they failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support

claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

The Truth Begins Emerging but the False and Misleading Statements Continue

Second July 29, 2021 Press Release

287. Also on July 29, 2021, the Company issued a different press release titled "Cassava Sciences Announces Positive Cognition Data With Simufilam in Alzheimer's Disease[.]" While the title, and the press release itself, framed the newly-released cognition data as being a positive development for the Company, observers recognized that the simufilam data presented showed that Cassava's product was no more effective than Biogen's product, Aduhelm.

288. Therefore, on this news, the price per share of the Company's common stock fell dramatically, from $135.30 at close on July 28, 2021, to $103.35 at close on July 29, 2021, to $69.53 at close on July 20, 2021. This was a two-day decline of $65.77, or approximately 48.6%.

289. Despite this revelation, the Individual Defendants continued to make or cause the Company to make false and misleading statements preventing the full truth from becoming known and keeping the Company's stock price artificially inflated.

290. On the same day in a July 29, 2021 press release titled, "Cassava Sciences Announces Positive Cognition Data With Simufilam in Alzheimer's Disease[,]" the Company and Defendants Barbier and Friedmann, still touted the data being presented as positive. The press release stated, in relevant part:

- **Simufilam Significantly Improves Cognition in Patients with Alzheimer's in Interim Analysis of Open-label Study at 9 Months**
- **Cognition Improved 3.0 Points on ADAS-Cog at 9 Months (p<0.001)**
- **Cognitive Improvements Track with Biomarker Improvements**
- **No Behavior Disorders in Over 50% of Patients**
- **No Safety Issues**
- **Improvements in Cognition, Biomarkers and Behavior Suggest Highly Encouraging Treatment Effects**
- **Oral Presentation at AAIC Today**

> . . . Cassava Sciences, Inc. (Nasdaq: SAVA) ***announced positive clinical data today*** from an interim analysis of an open-label study with simufilam, the Company's investigational drug for the treatment of Alzheimer's disease.
>
> In a clinical study funded by the National Institutes of Health (NIH), simufilam significantly improved cognition in Alzheimer's patients, with no safety issues. Simufilam improved cognition scores 3.0 points on ADAS-Cog11, an 18% mean improvement, baseline to month 9 (p<0.001). This interim analysis summarizes clinical data from the first 50 patients with mild-to-moderate Alzheimer's disease who completed 9 months of open-label simufilam treatment.
>
> Cassava Sciences believes today's data is the first report of significant cognitive improvements at 9 months that also track with robust improvements in biomarkers in patients with Alzheimer's.
>
> ***"We are very pleased with the overall consistency of data," said Remi Barbier, President & CEO. "Simufilam improved cognition, biomarkers and behavior, a***

triple-win for study participants. These clinical data combined with a clean safety profile and easy oral administration suggest highly encouraging and durable treatment effects for people living with Alzheimer's disease."

Alzheimer's is a progressive disease. Cognition will always decline over time. In patients with mild-to-moderate Alzheimer's disease, cognition scores decline over 4 points on ADAS-Cog over 9 months with over 90% certainty, as reported by the science literature[1].

Simufilam *improved* ADAS-Cog scores in 66% of patients at 9 months. An additional 22% of patients declined less than reported in the science literature at 9 months. Cognition outcomes suggest simufilam's treatment effects were broad-based.

Alzheimer's is often accompanied by behaviors disorders, such as anxiety, agitation or delusions. These may become more frequent as disease progresses. Simufilam *reduced* dementia-related behavior at 9 months on the Neuropsychiatric Inventory (NPI), a clinical tool widely used to measure changes in dementia-related behavior.

- At baseline, 34% of study subjects had no neuropsychiatric symptoms.
- At month 6, 38% of study subjects had no neuropsychiatric symptoms.
- At month 9, over 50% of study subjects had no neuropsychiatric symptoms.

The safety profile of simufilam in the interim analysis is consistent with prior human studies. There were no drug-related serious adverse events. Adverse events were mild and transient.

"Today's data with simufilam suggests disease modification," added Nadav Friedmann, PhD, MD, Chief Medical Officer. "It appears the drug's unique mechanism of action has potential to provide transformative treatment benefits following 9 months of dosing."

In February 2021, Cassava Sciences reported that simufilam improved cognition scores by 1.6 points on ADAS-Cog11, a 10% improvement, following six months of open-label treatment.

(Italicized emphasis added.)

291. The statements in ¶ 290 were false and misleading because they failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using

postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

August 24, 2021 Press Release

292. On August 24, 2021, the Company issued a press release titled, "Cassava Sciences Announces Agreement with FDA on Special Protocol Assessments (SPA) for its Phase 3 Studies of Simufilam for the Treatment of Alzheimer's Disease[.]" The press release contained a statement by Defendant Barbier and stated, in relevant part:

> . . . Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer's disease, announced today that it has reached agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for both of its pivotal Phase 3 studies of oral simufilam for the treatment of patients with Alzheimer's disease.
>
> These SPA agreements document that FDA has reviewed and agreed upon the key design features of Cassava Sciences' Phase 3 study protocols of simufilam for the treatment of patients with Alzheimer's disease.
>
> ***"I believe these SPAs mark a meaningful and encouraging milestone for Cassava Sciences," said Remi Barbier, President & CEO. "The SPAs underscore our alignment with FDA on key scientific, clinical and regulatory requirements of our Phase 3 program of simufilam in Alzheimer's disease."***

> Cassava Sciences also reaffirmed prior guidance to advance simufilam into a Phase 3 pivotal program in Alzheimer's disease in Fall 2021.

(Emphasis added.)

293. The statements in ¶ 292 were false and misleading because they failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

August 24, 2021 Citizen's Petition

294. On August 24, 2021, after the market had closed, the Citizen's Petition was submitted to the FDA and challenged the accuracy and integrity of clinical data supporting simufilam became publicly available. The petition, dated August 18, 2021, requested that the FDA "halt the current clinical studies of Simufilam . . . pending audits of (1) the publications relied on

by Cassava in support of its scientific claims concerning Simufilam; (2) the IND [Investigation New Drug] application for Simufilam's use in Alzheimer's Disease; and (3) all clinical biomarker studies of Simufilam in Alzheimer's Disease."

295. The petition's "Statement of Grounds," section stated as follows in support of its request:

> Petitioner has enclosed with this Petition (and incorporates herein) a detailed technical report presenting ***multiple reasons to question the quality and integrity of the research supporting Cassava's claims about Simufilam's use*** for Alzheimer's Disease. In sum, that report explains:
>
> (1) ***All of the foundational science supporting Cassava's claims about Simufilam's use for Alzheimer's Disease comes from a series of papers with two common co-authors (Dr. Hoau-Yan-Wang at City University of New York and Dr. Lindsay Burns of Cassava).*** The studies of Drs. Wang and Burns were used by Cassava to obtain NIH grants and to open an Investigational New Drug (IND) application to study Simufilam. They form the foundation for the current clinical trials of Simufilam.
>
> (2) ***No other lab has confirmed Cassava's research connecting Filamin A to Alzheimer's Disease, nor has any other lab confirmed that Simufilam binds or modifies Filamin A or has effects in Alzheimer's Disease models.***
>
> (3) Close review of the data and analyses in the foundational research papers and Cassava's recent publications of clinical trial analyses presents primary areas of concern:
>
> a. The underlying papers of Drs. Wang and Burns involve extensive use of Western blot analyses to support their claims connecting Simufilam to Alzheimer's. ***Detailed analysis of the western blots in the published journal articles shows a series of anomalies that are suggestive of systematic data manipulation and misrepresentation.***
>
> b. Some of the foundational studies published by ***Drs. Wang and Burns make claims about Simufilam's effects in experiments conducted on postmortem human brain tissue. The methodology allegedly used in those experiments defies logic, and the data presented again have the hallmarks of manipulation.***
>
> c. Cassava's presentation of clinical biomarker data from the Phase 2b trials raises questions about the validity of the data. ***The CSF samples in this study were first analyzed by an outside lab, which found that Simufilam was***

> ***ineffective*** in improving the primary biomarkers end point and high variability in other biomarkers. ***But Cassava had these samples analyzed again and this time reported that Simufilam rapidly and robustly improved a wide array of biomarkers. Cassava has not fully published the data from this reanalysis, but a presentation poster that it published on July 26, 2021, which appears to describe aspects of that work, shows signs of data anomalies or manipulation***.
>
> (4) ***Six further aspects*** of the research by Drs. Wang and Burns are incompatible with scientific norms, and these claims ***raise further suspicions***.
>
> a. Remarkably High Affinity Binding Between PTI-125 and Filamin A.
>
> b. Remarkably High Affinity Binding Between Naloxone and Filamin A
>
> c. Isoelectric Focusing Experiments in Multiple Papers Indicate 100% of Filamin in Altered Conformation in Alzheimer's Disease and largely Restored to Correct Conformation by PTI125.
>
> d. Novel Blood Diagnostic SavaDx Represents Plasma Filamin A Level
>
> e. PTI-125/Simufilam Improves Memory in a Mouse Model of Alzheimer's Disease.
>
> f. PTI-125/Simufilam Blocks the Interaction Between B-amyloid and x7 – Nicotinic Acetylcholine Receptors.

(Emphasis added.)

296. The forty-two page "Statement of Concern Regarding the Accuracy and Integrity of Clinical and Preclinical Data Supporting the Ongoing Clinical Evaluation of Compound PTI-125, Also Known As Simufilam[,]" filed as an attachment to the petition and incorporated into it, further noted in its introduction, in relevant part:

> In this document, ***three primary concerns are raised***:
>
> - The validity of clinical biomarker data: Biomarker analysis from patients treated with simufilam in Cassava's double-blind study forms a primary basis of Cassava's claim that simufilam engages its target in the central nervous systems, but ***there are concerns about the integrity of this data. The CSF samples in this study were analyzed by an outside lab, which found that simufilam was ineffective*** in improving the primary biomarker end point and showed high variability in other biomarkers. ***However, Cassava Science had these samples bioanalyzed again and the data were finalized in an academic***

lab, which apparently refers to Dr. Wang. This re-analysis showed that simufilam rapidly and robustly improved a wide array of CSF biomarkers. Whereas Cassava has not fully published this reanalysis, Cassava's 26 July 2021 poster presumably describing aspects of that work shows signs of data manipulation.

- The integrity of western blot analyses: Western blotting was extensively used by Drs. Wang and Burns over the past 15 years to support their foundational scientific claims and underscores their SavaDx clinical plasma biomarker. ***Detailed analysis of the western blots in the published journal articles from Drs. Wang and Burns shows a series of anomalies. The extent of these anomalies forms a 15-year pattern that strongly suggests systematic data manipulation and misrepresentation.***

- The integrity of analyses involving human brain tissue: Simufilam is reported to bind to its target and modify a range of downstream molecules in experiments conducted on post-mortem human brain tissue from subjects with Alzheimer's disease and neurological controls. ***The same human brain specimens are used across the studies from 2008-2017, so the results are premised on human neurons remaining viable up to 13 hours after death, then being successfully reanimated after nearly 10 years in frozen archival without any advanced cryopreservation techniques. The complex, multi-step cellular processes the authors claim to observe in tissue that has been dead for a decade are contrary to a basic understanding of neurobiology. As with the western blot data, there are anomalies in the presentation of the data which again strongly suggests manipulation.***

(Emphasis added.)

297. The Citizen's Petition concluded by stating that: "the extensive evidence set forth in the enclosed report, which presents grave concerns about the quality and integrity of the scientific data supporting Cassava's claims for Simufilam's efficacy, provides compelling grounds for pausing the ongoing clinical trials until the FDA can conduct and complete a rigorous audit of Cassava's research."

August 25, 2021 Company Response

298. The next morning, before the market opened, Cassava issued a response to the Citizen's Petition. The Company's response stated as follows, in relevant part:

Fiction: ***Biomarker data is generated by Cassava Sciences or its science collaborators and therefore are falsified.***

Fact: ***Cassava Sciences' plasma p-tau data from Alzheimer's patients was generated by Quanterix Corp., an independent company, and presented at the recent Alzheimer's Association International Conference.***

Fiction: Plasma p-tau for one individual Alzheimer's patient increased by 235%, which was not shown in the scatterplot.

Fact: This patient's plasma p-tau increased by 38%, not 235%, as shown in a scatterplot.

Fiction: Tissue staining showing Abeta42 inside neurons shows treatment effects.

Fact: Yes, Abeta42 is indeed inside neurons prior to plaque formation.

Fiction: The author's Citizen's Petition to FDA dated August 18, 2021, is evidence of wrongdoing.

Fact: Five days after the Citizen's Petition, Cassava Sciences announced it had reached an agreement with FDA on Special Protocol Assessments (SPA) for its Phase 3 studies of simufilam for the treatment of Alzheimer's disease. The SPAs underscore alignment with FDA on key scientific, clinical and regulatory requirements of the Company's Phase 3 program of simufilam in Alzheimer's disease. Furthermore, a Citizen's Petition allows any party to raise safety/efficacy concerns with drugs the FDA is considering for approval, which is not the case for Cassava Sciences' simufilam.

Fiction: Extensive use of Western blot analysis is foundational to Cassava Sciences' research and therefore suspicious.

Fact: Western blot analysis is foundational to the biotechnology industry. Western blotting is a standard lab technique used world-wide to detect a protein of interest.

Fiction: Cassava Sciences' Western blots data appear overexposed and highly processed, evidence of image manipulation.

Fact: High quality bands are supposed to look sharp. Smudged bands can be evidence of inexperience, depending on levels of protein in the band.

Fiction: Western blots data are identical, more evidence of image manipulation.

Fact: The Western blots bands shown in the allegation are control bands. Control bands are supposed to be highly similar (since they show equal amounts of protein between lanes). Bands show clear differences when expanded. In addition, image

manipulation of control bands makes no sense since these would not change the end data.

Fiction: "Halo" effects in certain bands indicate fraud.

Fact: A "Halo" effects in certain bands is a direct result of very dense dark loading control bands.

Fiction: Unusual looking bands on Western blots were pieced together from multiple sources.

Fact: Proteins can and do stick to the side of a lane and migrate that way, resulting in 'candy-wrapper' appearance or other fictional images.

Fiction: Femtomolar binding affinity is unusual and suspicious.

Fact: Femtomolar binding affinity is a fundamental property of simufilam and may account for its relative potency and safety.

Fiction: Post-mortem brain tissue that is dead for a decade is unreliable.

Fact: Because of the inaccessibility of the human brain and its unavailability for biopsy, translational medicine can rely on post-mortem tissue. In our case, human brain tissue was collected within 6 hours of death, flash-frozen and stored at -80 Centigrade. This is a standard procedure for pathologists. Such tissue processing is also used in cancer and other fields. Cassava Sciences is not aware of an industry-wide 'expiration date' on human post-mortem brain tissue that is properly collected, processed and stored.

Fiction: Isoelectric focusing gels should not have crisp bands, which is evidence of fraud.

Fact: Quality isoelectric focusing gels often do have crisp bands.

Fiction: Changes in the Y-maze test for transgenic mice could be interpreted as a decline in cognition.

Fact: A panel of independent, peer-reviewers believe these changes represent an improvement, along with significant improvements in two other behavior tests.

Fiction: High-affinity binding of naloxone for filamin A is suspicious.

Fact: Naloxone binds the same site on filamin A. Of course, it will have high-affinity binding.

> **Fiction**: Isoelectric focusing experiments indicate 100% of filamin A is in altered conformation in Alzheimer's disease and is largely restored to correct conformation by simufilam.
>
> **Fact**: Cassava Sciences agrees. This nicely describes the mechanism of action for simufilam.

(Italicized emphasis added.)

299. Despite the Company's spin, the market received the news of August 24, 2021 and August 25, 2021 negatively, and the price per share of the Company's common stock dropped from $117.83 at close on August 24, 2021—the Citizen's Petition had not become public until after the markets had closed that day—to close August 25, 2021 at $80.86. This $36.97 decline marked approximately a 31.4% one-day decrease in value.

300. The statements in ¶ 298 were false and misleading because they failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented, but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam;

and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

301. Additionally, the statements in ¶ 298 were also false and misleading because they failed to disclose that: (1) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness—Quanterix merely conducted the biomarker tests which generated the raw data; and (2) that the company an individual patient who was removed from the 100 mg dose group resulted in missing plasma p-tau data and the patient had actually shown an increase of 150%, rather than the reported 38%.

302. Following Cassava's lampooning of the Citizen's Petition, Dr. Bik posted on her website that the Company's response regarding "the problematic Western blots ***are not very convincing.***" (Emphasis added.) She chided the Company for labeling valid concerns as "fiction" and for providing vague responses such as "control bands are supposed to be highly similar." Dr. Bik called on the Company to "present high-quality scans of the uncropped Western blot films."

303. On August 25, 2021, Dr. Bik tweeted "Whoa. $SAVA/@CassavaSciences response to (legit) allegations that Western blot bands look similar or spliced raised even more concerns."

304. On September 3, 2021, Defendant Barbier released a public statement agreeing that the only way to settle these allegations around the Company's "Western blot might be to go back to the original films and images." He nor anyone at the Company ever provided Dr. Bik with the "original films and images."

305. On November 23, 2021, *Fierce Biotech* released an article titled "Data Manipulation Expert Elizabeth Bik Compares the Tales of 2 Accused Biotechs: Cassava and Athira," in which Dr. Bik was quoted saying:

> [Cassava] released this statement where is had like facts and fiction. Basically, they called all these allegations fiction, and then they had facts, and ***some of these facts were clearly, in my opinion, fiction***, and it was ***not written by a person who had any knowledge about molecular biology or about blots in general***. It was very dismissing of all the concerns, while, in my opinion, the ***concerns had merit***.

(Emphasis added.)

306. On August 27, 2021, Quanterix issued a statement in response to Cassava, clarifying its involvement in the creation of the data the Company had presented at the Alzheimer's Association International Conference. Quanterix's statement said as follows, in relevant part:

> ***Cassava previously engaged Quanterix' Accelerator laboratory to perform sample testing based on blinded samples provided by Cassava. Quanterix or its employees did not interpret the test results or prepare the data charts presented by Cassava at the Alzheimer's Association International Conference (AAIC) in July 2021 or otherwise.***
>
> Quanterix is widely recognized for its commitment to business integrity and to upholding the highest standards of quality. Quanterix' Simoa technology provides exquisite sensitivity for detecting and measuring biomarkers across a wide range of disease states, including neurology, oncology, and infectious disease. The Simoa technology has been trusted by 24 of the top 25 top pharmaceutical companies, and Quanterix customers have described the use of Simoa technology in over 1,300 research papers and presentations worldwide.
>
> Quanterix harnesses the power of biomarkers with the latest detection solutions to enable a precision health vision of proactive, preventative healthcare and believes that, in doing so, can change the course of how diseases like Alzheimer's are currently studied and treated.

(Emphasis added.)

307. Cassava responded to Quanterix's above statement on the same day, August 27, 2021, by clarifying in a press release that:

> The Phase 2b clinical study was conducted by Cassava Sciences***. Quanterix' sole responsibility with regard to this clinical study was to perform sample testing, specifically, to measure levels of p-tau in plasma samples collected from study subjects.***
>
> "To ensure data integrity, ***it is standard industry practice to keep separate the people who generate the data from the people who analyze the data," said Remi***

> ***Barbier, President & CEO. "That certainly was the case here. Anything different is a distortion of the facts."***
>
> Quanterix' sample testing was conducted entirely by its employees. Quanterix' employees were blind to treatment group, i.e., they did not know which samples were from placebo, or simufilam-treated patients. Quanterix conducted sample testing, then sent raw data to Cassava Sciences for analysis of treatment effects. Eventually, Cassava Sciences presented these data in a poster presentation at the Alzheimer's Association International Conference (AAIC) in July 2021. In keeping with scientific authorship guidelines, prior to submitting the abstract to AAIC, Cassava Sciences received permission from Quanterix to include its lab personnel in the author list.

(Emphasis added.)

308. Additionally, Dr. Bik posted on her blog that same day announcing she had taken "a look at the problematic photos included in the [Citizen's Petition] report, and ***agree[d] with most of those concerns***," on top of finding "some additional problems." Dr. Bik noted that "[a]t least five other articles from the Wang lab at CUNY appear to show image concerns as well." Dr. Bik's damning announcement implicated Cassava, Dr. Burns, and Dr. Wang.

309. On this news, the Company's share price declined by $12.51 per share—approximately 17.7%—from its August 26, 2021 closing price of $70.85 per share to close August 27, 2021 at $58.34.

August 30, 2021 Supplement to the Citizen's Petition

310. On August 30, 2021, a supplement to the Citizen's Petition (the "First Supplement") was filed with the FDA in order to "re-emphasize… concerns about the **clinical data** and supplement those concerns with new information identified by us and others in the scientific community, since the publication of my petition."

311. The First Supplement detailed concerns regarding the July 26 poster the Company used to present at the AAIC. In particular, it noted data discrepancies in **Figures 4** and **5**, including the fact that "Figure 4 contained 17 points yet the same group in Figure 5 contained 18 points."

Per the First Supplement's calculations, the missing value for the 100 mg group (represented in **Figure 4**) changes the Company's reported p-value "of ~0.01 to a **non-significant p-value of 0.08**." (Emphasis in the original.)

312. The First Supplement furthered that **"[w]hen recalculating using paired *t*-tests accounting for that switch, the p-values for the 50 mg and 100 mg treatment groups become larger (0.034 and 0.15, respectively**). Because the study evaluated multiple biomarkers, **neither of these groups would be considered statistically different from placebo** when accounting for multiple comparisons." (Emphasis in the original.)

Dr. Bik's Concurrence

313. Also on August 30, 2021, Dr. Bik posted on her website that she "agree[d] with those concerns" detailed above regarding the misstated data of the AAIC poster. In addition, Dr. Bik found if the 150% outlier data had "been included in the 100 mg treatment group, the average change-from-baseline would change from -17% to around -3%, which is a ***much less spectacular reduction of plasma P-tau181 levels than claimed by the company."*** (Emphasis added.)

314. On this news, the Company's share price declined by $5.08 per share from its August 27, 2021 closing price of $58.34 per share to close August 30, 2021 at $53.26.

September 3, 2021 Press Release

315. On September 3, 2021, the Company issued a press release responding to the new allegations laid out by the First Supplement and Dr. Bik. The press release quoted Defendant Barbier, stating:

> "Let me be very clear: I think these allegations are false," said Remi Barbier, President & CEO. "The allegations claim our science is improbable, unexpected and unique to Cassava Sciences, and therefore it's all an elaborate fraud. By these criteria, all drug innovations are fraudulent. We intend to vigorously defend ourselves and our stakeholders against false and misleading allegations."

316. In the published transcript of Defendant Barbier's remarks, he stated that "[t]hese allegations are not only false, I also think they are misleading." He asserted that the Company "[does] not invent stuff out of thin air."

317. Regarding Dr. Wang, Defendant Barbier told investors that "Prof. Wang has also been a scientific collaborator to Cassava Sciences for about 15 years on Alzheimer's program. Over 15 years, you get to know someone very well. Based on our long-term scientific relationship with Prof. Wang, we support his scientific integrity and ethics in the strongest possible terms."

318. Notably, however, Defendant Barbier admitted that some of the issues brought up in the Citizen's Petition were factual. For example, Defendant Barbier stated that there were in fact "visual errors" in "one publication and one poster presentation," but hedged that the errors were "not material" and that the "data analysis [was] correct." Defendant Barbier admitted that in the 2017 *Neurobiology of Aging Paper*, "**Figure 12** contains an image showing 12 control bands. It should show 13." While this issue was pointed out by the Citizen's Petition, Defendant Barbier continued to state that "[t]he data analysis was based on all 13 control bands," asserting it was merely a visual error with no impact on the conclusion.

319. Moreover, Defendant Barbier also admitted that there were data point errors in the July 26, 2021 AAIC poster, just as the Citizen's Petition had pointed out in **Figures 4** and **5.** Again, however, Defendant Barbier asserted that while the data was visually left off, they were "included in the data analysis."

320. On Twitter, Dr. Bik rebutted Defendant Barbier's comments, stating:

> Leaving out a value that does not fit the hypothesis cannot be brushed off as just "removing an outlier" that was left in by Error.
>
> That is a very serious and intentional action that needs much more explanation. Also, it is hard to imagine a scientist with 3 sets of ~30 data points who accidentally

leaves out 2 values in one set and adds an additional value in another set. The data gets plotted from the data (in R). It is not just an artist painting a "visual".

321. Defendant Barbier's statements in ¶ 318 were false and misleading because he failed to acknowledge to the public that the data errors were not just "visual."

322. On this news, the Company's stock price fell from $54.35 per share at the closing of trade on September 2, 2021 to $50.20 per share at the closing of trade on September 3, 2021.

September 9, 2021 Second Supplement to the Citizen's Petition

323. On September 9, 2021, a second supplement to the Citizen's Petition was filed with the FDA (the "Second Supplement"). The Second Supplement detailed five new major concerns based on the Company's recent public remarks.

These five major concerns are:

1. Cassava claims not to have the Western blots that comprise the original data for the Phase 2a biomarker study.

2. Cassava publicly claims that the initial Phase 2b biomarker reanalysis and "redo" were performed by an "outside lab," when it appears that they were both done by Dr. Wang, whose research the company separately describes as being done "in-house."

3. Cassava publicly stated that the initial and redo analyses of the phase 2b study were done by two distinct "outside labs." In fact, the initial and the redo analyses appear to have both been done in-house by Dr. Wang. Cassava's preprint, describing the phase 2b biomarker data, contradicts the company's public statements and clarifies that Dr. Wang and his colleagues at CUNY alone conducted the biomarker redo analyses. Cassava's trial protocol submitted to ClinicalTrials.gov also states that CSF samples for the first analysis were sent to Dr. Wang for biomarker assays. If Dr. Wang did both the initial and redo analyses, this is inconsistent with Cassava's public claims that these tests were done by different outside labs.

4. Many of the results from Dr. Wang's Phase 2b redo have what appear to be data manipulation or GROSS LAB ERRORS—values incompatible with standards for these type of analyses—which raises additional questions about the validity of the biomarker results associated with the redo.

5. The Phase 2a and 2b biomarker studies were likely key elements of the Special Protocol Assessment (SPA) submitted to the FDA. If the Phase 2a or 2b studies were misrepresented, that SPA should be rescinded in accordance with applicable law and regulations.

The Truth Continues to Emerge As Defendants Attempt to Cover Their Tracks

November 4, 2021 Journal of Neuroscience Exculpatory Statement

324. On November 4, 2021, Cassava announced it was halting the trading of its stock. After doing so, the Company issued a press release announcing that "[Cassava] has been informed by the *Journal of Neuroscience* that there is no evidence of data manipulation in an article it published in July 2021 describing a new approach to treating Alzheimer's disease." The Company stated it had provided the journal with "raw data for the article, including images of original, uncropped Western blots." The press release noted, however, there was "[o]ne human error that does not impact data conclusions" for which the journal was issuing a correction for.

325. Defendant Barbier trumpeted, "I've never doubted the integrity of our people or science… We remain focused on conducting a Phase 3 clinical program of simufilam in people with Alzheimer's disease. It's an important endeavor, notwithstanding pundits who may be louder than they are learned. We'll stay the course until the job is done."

326. On this news, the price of the Company's stock surged by $26 to a closing price of $84.40 end of day November 4, 2021.

327. The statements made in ¶¶ 324-326 were false and misleading when made because they failed to disclose that the data submitted to the journal for inspection was not the "raw data… including images of original, uncropped Western blots," instead it was manipulated data as discovered by Dr. Bik and others following the announcement.

328. Indeed, on November 10, 2021, the *Journal of Neuroscience* issued an Erratum, confirming concerns raised by Dr. Bik. For example, just as Dr. Bik had voiced, the Erratum noted

that **Figure 8B** contained a duplication, stating that "[t]he top left image in the Western blot panel in Figure 8B, representing Aβ42 immunostaining of FCX of the Aβ42 group, was duplicated from the top middle image in Figure 8A, representing immunostaining of the FCX of the PTI-125+ Aβ42 group."

329. Moreover, the Erratum stated that "[t]o provide clarity on the integrity of bands in Figures 6, A and B, and 9A, the following images have been made available by the authors." The images were described as the "original, uncropped blots of loading control bands…."

330. As noted in the supplement to the Citizen's Petition filed with the FDA on November 17, 2021 (the "Third Supplement") Drs. Bredt and Pitt, however, proved the claims by the erratum to be false, highlight that:

- The erratum addresses concerns with images in Figures 6A, 6B, and 9A. The erratum does not address other Figures (e.g., Figures 1, 2, 5, 10, and 11) that have also been noted for apparent data manipulation.

- The images supplied as "originals" do not show the edges of the x-ray film from which they were said to have been obtained. Thus, they are ***not*** the "complete" original images.

- The images supplied as "originals" do not show molecular weight markers. Molecular weight markers are standard proteins that are always run in one lane of the gel so that the relative position of the bands-of-interest can be sized. Since no molecular weight markers were shown, the images supplied as "originals" appear to be, at best, cropped versions.

- The published erratum reports that for Fig. 9A, "The left image is the higher-resolution image with the additional bands cropped out, as seen in the full image on the right." The supplied "original" images are of lower resolution than the images published in the 2012 paper. Resolution of the original should be higher, not lower, than subsequent ones.

- Several forensic analyses suggest that the supplied "original" images are composites of cropped images, and thus not original.

331. The Third Supplement furthers that "[s]everal forensic analyses suggest that the suppled 'original' images are composites of cropped images, and thus not original."

332. Dr. Bik, for one, noted that the so-called "original, uncropped" blot scans for Figures6A, 6B, and 9A (pictured below) "appear to show just the cropped blots on a larger area, with none of the expected MW marker positions, labels, or edges of the X ray film visible."

2 • The Journal of Neuroscience, 0, 2021 • 00(00):1–2

Figure 6*A* and 6*B* – IRβ uncropped blot

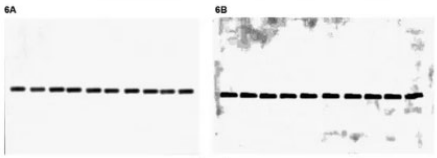


Figure 6.

Figure 9*A* – β-Actin uncropped blot

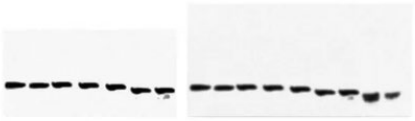


Figure 9.

DOI: 10.1523/JNEUROSCI.2154-21.2021

333. Dr. Bik's critiques of the erratum on November 10, 2021, began a free fall for the Company's stock price. It fell from $78.41 per share at the closing of trade on November 9, 2021 to $69.40 per share at the closing of trade on November 10, 2021. The stock continued to drop over the course of the next week and dipped to $47.07 per share on November 17, 2021 following the Third Supplement.

334. Regarding Figure 9A, Dr. Bik revealed an alteration in the background of the image (shown below) by adjusting the contrast on the purported "original." Dr. Bik noted that this "is a potential ***big concern*** in the provided original β-actin blot for **Figure 9A.** The authors/journal say the blot on the right shows the original blot with two additional lanes on the right. But I see a box around those lanes that matches the published blot's size."

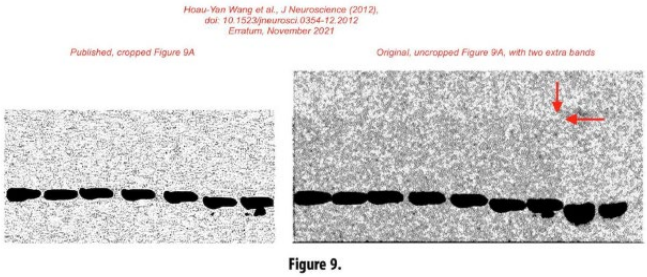
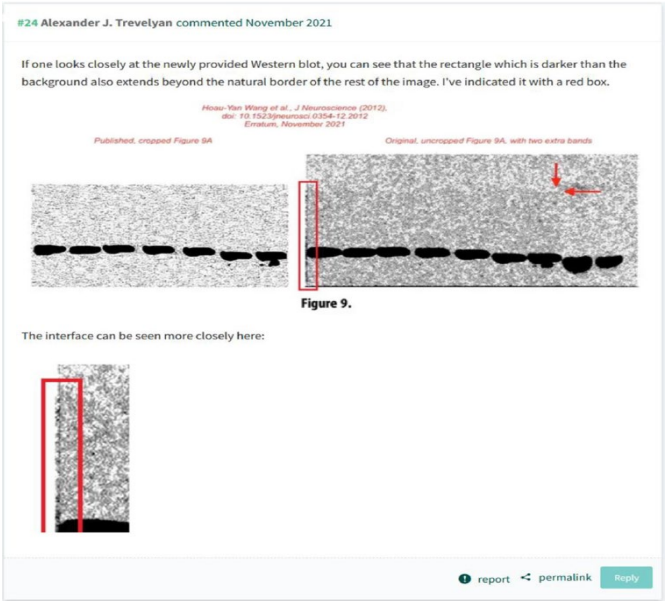


Figure 9.

335. Alongside Dr. Bik, Alexander Trevelyan, Ph.D., noted that "the rectangle which is darker than the background also extends beyond the natural border of the rest of the image. I've indicated it with a red box." (See below.)[13]



336. As the Third Supplement pointedly stated "[t]he bottom line is [Cassava] does not appear to have provided the Journal of Neuroscience 'original, uncropped Western Blots' as represented in its 11/4/2021 press release, so the journal could not have exonerated them, as they so dramatically suggested."

[13] Dr. Bik and Trevelyan's discussion about the doctored images can be seen in full at: https://pubpeer.com/publications/F91E0D22B887598445BB1F908393EE.

337. The Third Supplement furthered that the "company appears to have knowingly taken the published image… blurred it a bit, and then photoshopped it onto a slightly different canvas to 'create' the image …." Indeed, Cassava and Dr. Wang ***did not*** provide the *Journal of Neuroscience* with "original, uncropped Western blot data."

338. The Securities Class Action obtained emails between Dr. Wang and the *Journal of Neuroscience*'s edit-in-chief stating that Dr. Wang found it "more difficult than… anticipated to find the blots" and accordingly, Dr. Wang instead provided a "PowerPoint containing the requested uncropped blots."

339. Accordingly, Dr. Wang's inability to find the original data is a poor excuse and, according to standards set by the ORI, possibly constitutes "research misconduct." Indeed, as ORI lays out, "in the case where an image lacks authenticity, the absence of the original data can be used as evidence of possible research misconduct and sufficient justification to conduct further fact finding." Additionally, the PowerPoint containing the uncropped blots does not meet the ORI's standard for authentication which requires "access to the original data."

340. Further email communications obtained by a FOIL in the Securities Class Action reveal that both Cassava and Dr. Burns were involved in perpetuating this fraud. On September 30, 2021, Dr. Burns sent the editor-in-chief of *Neuroscience* an email stating "we have already responded to JNS with original blots…." Yet, as clearly laid out above, Drs. Burns and Wang never provided the *Journal of Neuroscience* with original blots. And now here they continue to perpetuate their fraud by insisting to *Neuroscience* that they had.

341. On December 17, 2021, the *Journal of Neuroscience* announced it was changing its Editorial Note into an Expression of Concern. Due to the concerns of Dr. Bik, the *Journal of Neuroscience* noted that:

> The editors have been made aware of concerns about Western blots in this study ***including*** those published with the article's erratum (Wang et al., 2021). These and other concerns are currently under investigation by the academic authorities at the [CUNY]. JNeurosci will await the outcome of that investigation before taking further action.

342. The *Journal of Neuroscience*, however, did not stop there. Later that same day, the journal issued a separate Expression of Concern for Dr. Wang's paper "Dissociating β-Amyloid from α7 nicotinic Acetylcholine Receptor by a Novel Therapeutic Agent, S 24795, Normalizes α7 Nicotinic Acetylcholine and NMDA Receptor Function in Alzheimer's Disease Brain." The *Journal of Neuroscience* stated:

> JNeurosci is publishing an Expression of Concern for the article, "Dissociating β-Amyloid from α7 Nicotinic Acetylcholine Receptor by a Novel Therapeutic Agent, S 24795, Normalizes α7 Nicotinic Acetylcholine and NMDA Receptor Function in Alzheimer's Disease Brain," by Hoau-Yan Wang, Andres Stucky, JingJing Liu, Changpeng Shen, Caryn Trocme-Thibierge, and Philippe Morain, which appeared on pages 10961-10973 of the September 2, 2009 issue. The editors have been made aware of concerns about Western blots in this study. These and other concerns are currently under investigation by the academic authorities at the [CUNY]. JNeurosci will await the outcome of that investigation before taking further action.

343. On this news, the Company's stock price fell 15.6%, or $6.82 per share, between Friday, December 17 and Monday, December 20, 2020, to close at $36.77 per share.

November 15, 2021 Form 10-Q

344. On November 15, 2021, the Company filed with the SEC its quarterly report in its Form 10-Q for the quarter ended September 30, 2021 (the "Q3 21 Form 10-Q"), signed by Defendants Barbier and Schoen. In the Q3 21 Form 10-Q, the Company disclosed that "[c]ertain government agencies have asked us to provide them with corporate information and documents. We have been cooperating and will continue to cooperate with government authorities." The Company even asserted that "[n]o government agency has informed us that any wrongdoing has occurred by any party."

345. On this news, the Company's stock fell $8.29 per share to a closing price of $60.51 per share on November 15, 2021.

346. The Q3 21 Form 10-Q, however, failed to disclose that the agencies, such as the DOJ, SEC, and NIH, started investigations ***into the Company***. Additionally, that the particular DOJ action was a ***criminal investigation***.

347. On July 27, 2022, Defendant Barbier ultimately confirmed that the Company knew these agencies were investigating the Company. On that same date, the Company issued a press release stating: "In November 2021, Cassava Sciences ***previously disclosed*** that certain government agencies had asked for corporate information and at that time, the media widely reported on these prior disclosures."

November 17, 2021 Wall Street Journal Article

348. On November 17, 2021 the *Wall Street Journal* published an expose on Cassava, stating that "the [SEC] is investigating claims that [Cassava]… manipulated research results of its experimental Alzheimer's drug, according to people familiar with the matter." The article further noted that the SEC investigation opened following a meeting between the SEC and Drs. Bredt and Pitt. Additionally, the NIH and CUNY had opened an investigation into claims surrounding Dr. Wang's Cassava's potential research misconduct.

349. The *Wall Street Journal* article was the first time Drs. Bredt and Pitt, the authors of the Citizen's Petition, had revealed their identities. In the article, Defendant Barbier described the doctors' claims as "outlandish" and stated, "you would hope that someone in a position of authority is looking into the legitimacy of the allegations." Likewise, Defendant Barbier, frustrated, stated: "There is zero evidence, zero credible evidence, zero proof that I've ever engaged in, nor anyone I know, has ever engaged in funny business[.]"

350. The *Wall Street Journal*, however, had interviewed other scientists all of whom "said some images in the articles depicting experimental results appear to have been copied and pasted from other sources."

351. Defendant Barbier criticized the scientists means of examining Cassava's research, stating: "In order to make allegations on the scale that they have, in order for those allegations to be credible, you've got to look at the originals." The "originals" of course being something the Company has been unwilling to furnish, or in other instance such as with the *Journal of Neuroscience*, has lied about furnishing the originals.

November 17, 2021 Third Supplement

352. In the Third Supplement, Drs. Bredt and Pitt stated that "at least three of the nine biomarkers analyzed by Dr. Wang and published by Cassava for the Phase 2a study of simufilam in Alzheimer's disease also appear to have wildly anomalous baseline measures." The Doctors furthered that "[t]hese apparent biomarker discrepancies are so extreme that they suggest lab errors or manipulation." Even more damning was that *the Journal of Prevention of Alzheimer's Disease*,[14] which published Cassava's Phase 2a results, had done so "just 6 days after submission…." Such a quick turnaround left obvious questions regarding "the credibility and rigor of the journal's peer review process."

353. The Third Supplement also called into question the fact that Cassava claims to have "conducted seemingly undoable experiments." In relevant part, the Third Supplement stated:

> [T]he alpha7 version of the nicotinic acetylcholine receptor (nAChR) is central to simufilam's proposed mechanism in Alzheimer's disease. In their 2017 review (Neuroimmunology and Neuroinflammation **4**: 263), Drs. Burns and Wang state that "PTI-125 binds and reverses the altered FLNA conformation to prevent Aβ's signaling via α7nAChR and aberrant activation of TLR4, thus reducing multiple AD-related neuropathologies." Like most of their claims, this research is unique to

[14] This controversial paper was authored by Drs. Wang, Burns, Friedmann and Mr. Barbier.

> Drs. Wang/Burns/Cassava and relies heavily on Western blotting. These results are elaborated in Cassava's 2012 Journal of Neuroscience paper and their 2017 Neurobiology of Aging paper.
>
> A major problem with this is that international leaders in the nAChR field agree that there are no antibodies suitable for Western blotting of alpha7 nAChR in the brain (see: Moser et al. Evaluating the suitability of nicotinic acetylcholine receptor antibodies for standard immunodetection procedures Journal of Neurochemistry, 2007, 102, 479–492). Therefore, the alpha7 nAChR data that form a mechanistic foundation for simufilam seem scientifically undoable.

354. The Third Supplement expands that:

> "[t]his fundamental limitation for alpha7 nAChR Western blotting raises serious questions regarding the validity of Fig. 1A, Fig. 2A, Fig. 9A, Fig. 10A, and Fig. 12A in Cassava's 2012 Journal of Neuroscience paper—***the very same paper that Cassava heavily touted in a recent press release as having only one 'human error***.'"

(Emphasis added.)

355. Dr. Adrian Helibut had raised similar concerns on November 9, 2021, when he tweeted: "In Wang, 2021 (J Neurosci), Dr. Wang reports using two α7 nAChR antibodies in the Methods: SC-5544, & SC-65844. This is another impressive feat by Wang, because SC_65844 is an antibody to **α1** nAChR." Dr. Helibut further tweeted that Dr. Wang in his 2017 paper *Neurobiology of Aging*, had "AGAIN claim[ed] to detect a7 nAChR / CHRNA7 using SC-658444."

356. Dr. Helibut's concerns were further expounded upon in the Third Supplement. As the supplement explained:

> Western blots rely on antibodies that recognize specific proteins. Thus, an antibody to the alpha1 nAChR does not recognize the alpha7 nAChR. The alpha1 nAChR is primarily found in muscle tissue and not in brain. Using an alpha1 nAChR antibody to detect alpha7 nAChR in brain is senseless. It would be like checking for Covid-19 infection with a pregnancy test kit.

357. The Third Supplement took Dr. Helibut's concerns even a step further and noted that in Drs. Wang's and Burns' 2012 *Journal of Neuroscience* paper, they "claim to use two

antibodies from Santa Cruise Biotechnology. One is catalog # SC-5544, which does not work for Western Blotting at all."

358. Additionally, Drs. Wang and Burns "mention antibody catalog # SC-65844 in their 2012 Journal of Neuroscience paper. ***However, Santa Cruz Biotechnology sells this to detect the lpha1 nAChR, not the alpha7 nAChR.***" (Emphasis added.) As the Third Supplement concludes, "all their purported alpha7 nAChR Western blotting research in the brain is ***seemingly undoable.***" (Emphasis added.)

359. On this news, Cassava's stock price fell to $47.07 per share on November 17, 2021, representing a decline of 23.7% or $14.62 per share.

December 8, 2021 Citizen's Petition Supplement

360. On December 8, 2021, a fourth and final supplement was filed to the Citizen's Petition with the FDA (the "Fourth Supplement"). In the Fourth Supplement, Drs. Bredt and Pitt centered concerns on Cassava's foundational 2017 paper "PTI-125 binds and reverses an altered conformation of filamin A to reduce Alzheimer's disease pathogenesis" published in the *Neurobiology of Aging*. The doctors explain that their "re-inspection of the Methods section for this crucial experiment shows seemingly ***irrefutable evidence of data manipulation/fabrication***." (Emphasis added.) For one, they note that Drs. Wang and Burns' paper is the only "direct binding [study] between PTI-125 and filamin A [to] have been reported." They further detail their concerns that:

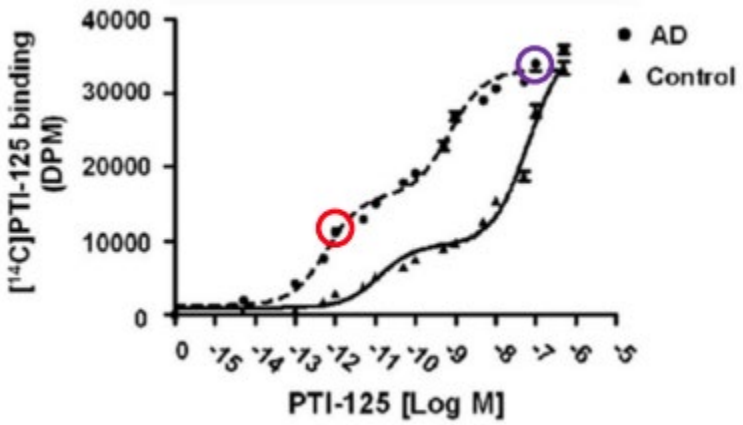
> The section states: "PTI-125's affinity for FLNA was determined in immunopurified FLNA using [C14]PTI-125 (57.7 Ci/mmol) …. Briefly, a binding curve was generated by incubation of 0.1 µg immunopurified FLNA from control or AD hippocampus …" Importantly, the binding experiments used PTI-125 labeled with carbon-14 [C14], which has a relatively low specific activity (rate of decay). This physical law makes [C14] useful for carbon dating, but ***completely unsuitable for detecting high affinity binding like that claimed for PTI-125 and filamin A.***

(Emphasis added.)

361. The paper furthered, detailing three "of the many major problems." First, the paper asserted that "Claimed Specific Activity for [C14] PTI-125 is ~1000 greater than Physical Laws Allow." The paper expands:

> Cassava states that their [C14] PTI-125 has a specific activity 57.7 Ci/mmol. However, pure [C14] has a specific activity of 62.5 mCi/mmol = 0.0625 Ci/mmol. This is the upper limit for a molecule with one [C14] substitution. Assuming one [C14] as is likely, ***Cassava's claimed specific activity for PTI-125 is ~1000 times higher than theoretically possible.*** Such an inexplicable error would create insurmountable problems and invalidate the study.

362. Second, the paper asserts that "FLNA Binding [C14] PTI-125 Could Maximally Yield 47 DPM vs >30,000 DPM Claimed in Fig 1B." The Fourth Supplement explains that "[b]ecause [C14] has intrinsically low specific activity (0.0625 Ci/mmol), it does not yield sufficient "counts" (DPM, disintegrations per minute) to reliably detect receptor binding." Based on calculations, Drs. Bredt and Pitt concluded that PTI-125 has a "47 DPM maximum" which "dramatically clashes with ~30,000 DPM claimed by Cassava scientists in Fig. 1B (see purple circle [included below])"



363. Third, the Fourth Supplement stated that "[C14] PTI-125 Cannot Be Used to Detect 1 pM FLNA Binding Affinity." As the Fourth Supplement explained, "[t]he low specific activity of [C14] precludes its utility to measure ultrahigh affinity binding… for Cassava to detect 10,000 DPM (red circle in Fig 1B), they would require 10,000 DPM ÷ 137 DPM / liter = 73 liters." Yet, "Cassava's binding assays surely were performed in much smaller volumes, and likely used **<5mL**, if the experiments were done at all." (Emphasis in original.)

364. The Fourth Supplement concluded that "**the numerous elementary problems with Cassava's experiments raise troubling questions about whether simufilam binds to filamin A at all.**" (Emphasis in original.) As such, the "[f]atal flaws in in these critical binding experiments, ***which form the foundation for [Cassava's] key investigations,*** raise serious questions about Cassava's hypotheses that filamin A is relevant to Alzheimer's disease and about whether simufilam affects filamin A."

365. On this news, Cassava's stock price dropped to $45.86 at the closing of trade on December 8, 2021. This represented a decline of 8.2% or $4.12.

December 20, 2021 Press Release

366. On December 21, 2021, Cassava issued a press release touting that "it had been informed by *Neuroscience* journal there is no evidence to support claims of data manipulation in a 2005 paper authored by the Company and its scientific collaborators."

367. Further, the release quoted Defendant Barbier, who stated:

> "Another science journal has cleared us of allegations…. This clearance is from an independent third party who is neutral and expert in the field. This reinforces my conviction that false and misleading allegations of scientific misconduct being made against us are simply designed to enrich those making them. People who seek to profit from false allegations may not comprehend the harm they are causing the Alzheimer's community, or perhaps they simply don't care. Leaving a trail of destruction in their wake in the quest for profit, with little concern for patients or

> their caregivers, is a twisted form of money-making and the opposite of what people with dementia deserve."

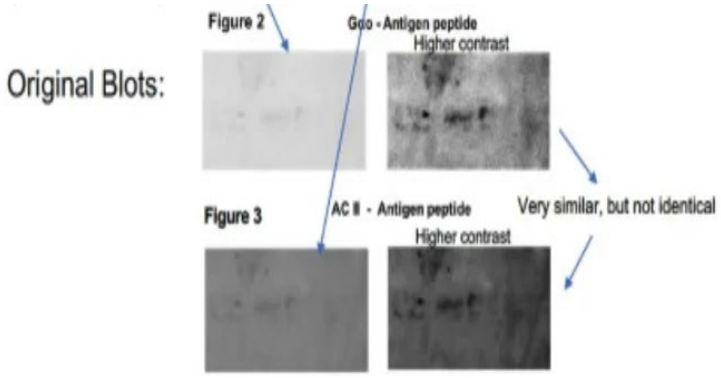
368. Included in the press release was a quote from the editor's note from the *Neuroscience* journal, stating:

> "In response to allegations of data manipulation in an article published in Neuroscience Vol 135, Issue 1, 2005, Pages 247-261, and following COPE (Committee on Publication Ethics) guidelines, the journal asked the authors for images of the original, uncropped Western blots from this study. After careful examination of these original material, Neuroscience found no evidence of manipulation of the Western blot data or other figures of this publication."

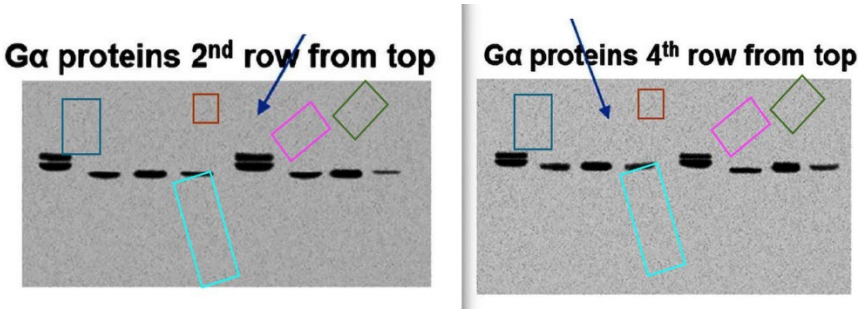
369. Omitted from the press release, however, was a line from the editor's note, stating that "[i]f any subsequent information arises from an institutional investigation, this will be considered once available."

370. The statements made in ¶¶ 366-369 were false and misleading when made because, contrary to representations to investors, Drs. Wang and Burns had failed to provide "original, uncropped" Western blots to the journal, as detailed further below. As explained by Dr. Bik in a December 20, 2021, Tweet, "[t]he provided uncropped blots should actually be X-ray films, as stated in the paper. Instead, the authors provided images without blot edges, labels or markers."

371. In a subsequent Tweet, Dr. Bik attached the image shown below and stated "I would argue these show the exact same blot, albeit at different resolution. Was the editor fooled here?"



372. In Dr Bik's opinion, what was "even more concerning" was that "the provided originals for Figure 5 [see below] all show very similar backgrounds. They look like the published blots projected on the same background, perhaps similar to what happened with the J Neuroscience paper."

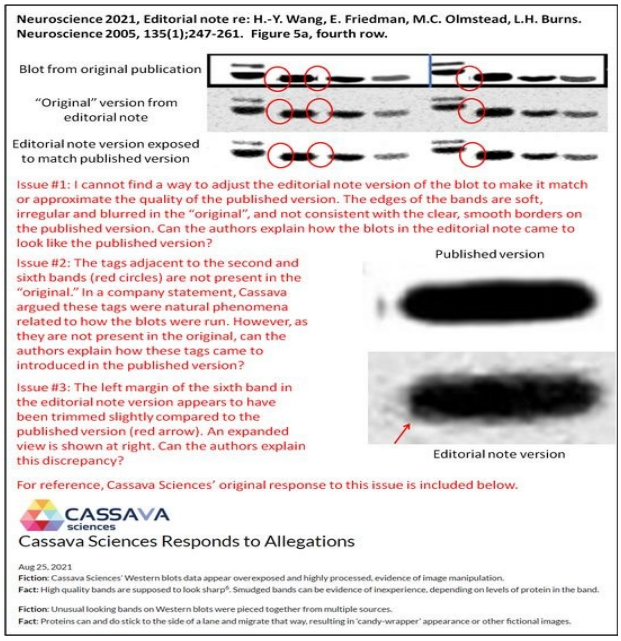


373. Dr. Bik took her concerns to PubPeer, again noting that the original blots for Figure 2 and Figure 3 "look very similar." She furthered that [t]hey are presented at different resolution/compression and crop, but they do not take away my concern that the top Gao panel in Figure 2 is very similar to the ACII panel in Figure 3."

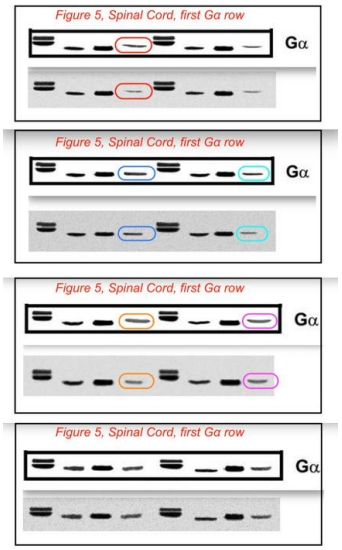
374. Dr. Bik additionally recognized concerns of the original blot provided for Figure 5. She noted:

> None of these blots look like the expected uncropped X-ray films; there are no marker lanes or labels, or edges of the blot visible. Yet, the article state the blots were exposed to X-ray films. How could the authors then provide scans of blots?
>
> Even more concerning, the blots provided in this Editorial Note appear to show very similar background patterns, albeit shown at different resolutions. How can the authors explain that?

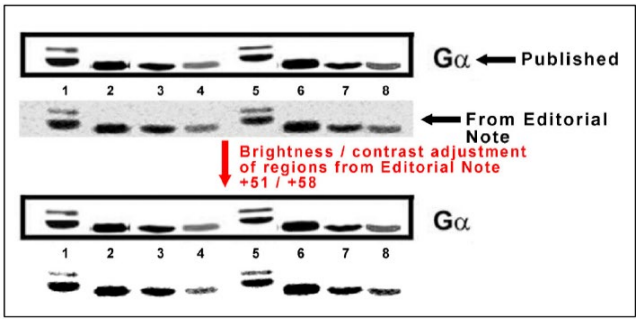
375. Dr. Bik also detailed concerns for Figure 5a, which are depicted below:



376. Dr. Bik also detailed concerns about discrepancies for Figure 5B, noting that "[c]omparing the published Gα rows to the provided original [see below], the bands in the fourth and eight [sic] lanes in particular do not always seem to match each other. I have highlighted those here with rounded boxes of the same color [depicted below]."



377. Similarly, the published image and the Editorial Note image feature discrepancies in the bands for lanes 4 and 8 (depicted below). Accordingly, the bands appear to have been altered with an image-processing software.



378. Further, emails obtained from a FOIL request between *Neuroscience* and Cassava's scientists, many of which confirm suspicions. On November 16, 2021, Dr. Burns emailed the editor-in-chief of *Neuroscience* stating that "[w]e are still looking for the original blots in backup drives, since the original hard drive melted years ago."

379. Then on November 15, 2021, the editor-in-chief of *Neuroscience* informed Drs. Wang and Burns that the journal was going to publish an Expression of Concern until the conclusion of the CUNY investigation. Unbeknownst to the public, *Neuroscience* ultimately decided against issuing the Expression of Concern.

January 3, 2022 Molecular Neurodegeneration Retraction

380. On January 3, 2022, the journal *Molecular Neurodegeneration* announced it was retracting an article titled "Calcium-dependent cytosolic phospholipase A2 activation is implicated in neuroinflammation and oxidative stress associated with ApoE4," of which Dr. Wang was included as a listed author. The retraction stemmed from issues in the Western blots depicted in Figure 9 which were first brought up in September 2021 by a number of individuals, including Dr. Bik, on PubPeer. The retraction noted that "concerns have been raised regarding the data presented in Fig. 9" so the authors "agree[d] to this retraction."

381. On January 3, 2022, Dr. Hussein N. Yassine, the papers corresponding author, commented in the PubPeer thread that:

> We have been notified of these irregularities in Figure 9. ***We do not have a clear explanation for them***. We have consulted with the publisher and journal. ***All authors agreed to retract the paper*** and resubmit without figure 9. Ongoing experiments are conducted to replicate experiments in Figure 9 to ensure the rigor and validity of the findings.

(Emphasis added.)

382. On January 20, 2022, Alexander Trevelyan PhD posted on Twitter: "I have received confirmation from Molecular Neurodegeneration that [Dr. Wang] did indeed attempt to provide apparently manipulated images to the journal, but that they did not accept them. Original blots were requested but Dr. Wang could not provide them."

383. Additionally, attached to the Tweet was an image of an email Mr. Trevelyan had received from the journal which read:

> The data of the integrity concern is Fig 9 of the paper, which was added in revision to address reviewers' concerns, and these data were not produced in DR. Yassine's lab, but a "newly added" author for that round of submission, Dr. HY Wang from the City College of New York. When the potential integrity issue was called to our attention, Dr. Yassine requested the original blot images from Dr. HY Wang for MN's editorial team and Springer Nature's Research Integrity Group to examine. ***Unfortunately, these "original" blot images from Dr. HY Wang also had visible signs very much looking like image manipulation, and Dr. Wang said he couldn't find other images from the repeated experiments.*** So, yes, Dr. HY Wang did provide a few images that he said were the original blot images; and no, we don't think [it was raw data]."
>
> * * *
>
> After reviewing the "original" blot images provided by Dr. HY Wang, all the authors, editors, and our publisher agreed retraction is the right call in this case.

(Emphasis added.)

February 10, 2022, FDA Response Letter

384. On February 10, 2022, the FDA rendered its decision regarding the Citizen's Petition. The FDA denied the Citizen's Petition because of procedural error, stating:

> We take the issues you raise seriously. Please note that your Petitions are being denied solely on the grounds that your requests are not the appropriate subject of a citizen petition. ***This response does not represent a decision by the Agency to take or refrain from taking any action relating to the subject matter of your Petitions.***

(Emphasis added.)

385. On the same day, the Company issued a press release titled "FDA Denies Citizen Petitions Filed on Behalf of Short Selling Clients." In it, Defendant Barbier touted that this meant the allegations were proven false, stating: "This news is very welcome but not surprising…. We said from the outset that the allegations are false. I think the message may be that the FDA's citizen petition privilege is not to be trifled with by stock market participants."

386. Defendant Barbier continued to leverage the FDA's denial as absolution of any wrongdoing. On April 27, 222, during a Q&A portion at the B. Riley Securities Conference, Defendant Barbier was reported as stating the "FDA denied the petition ***because they did not find any evidence of fraud.***"

387. The statements in ¶¶ 380-386 were false and misleading because Defendant Barbier intentionally misrepresented to investors and the market what the FDA's decision reflected. While Defendant Barbier persisted in touting it as absolution, the very own words of the FDA do everything but. Quite specifically in the letter, the FDA stipulates that "[t]his response does not represent a decision by the Agency to take or refrain from taking any action relating to the subject matter of [the] Petitions."

March 22, 2022 Expression of Concern

388. On March 22, 2022, Drs. Wang's and Burns' 2017 paper "PTI-125 binds and reverses an altered conformation of filamin A to reduce Alzheimer's disease pathogenesis" received an Expression of Concern from the journal *Neurobiology of Aging*. The Expression of concern stated:

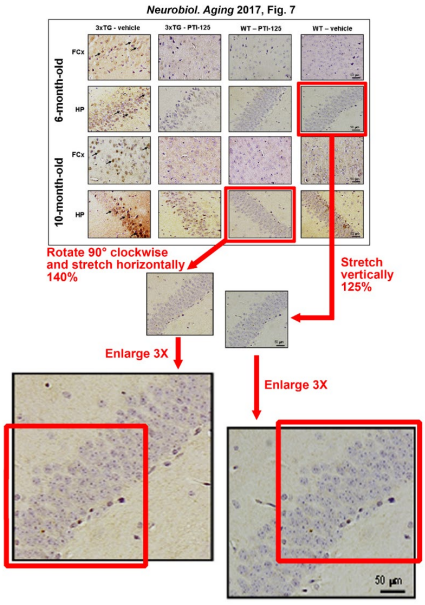
> A reader has made the editors aware of concerns regarding the above-referenced report published at Neurobiology of Aging. These issues were conveyed to the authors, who provided a detailed response, including images of relevant uncropped western blots and photomicrographs, as the editor requested. The material was evaluated by an independent expert with relevant methodological expertise, the manuscript was scanned by AI-based figure proofing software (i.e., Proofig), and all available input was considered by the handling editor and Editor-in-Chief.

389. While the Expression of Concern "did not find compelling evidence of data manipulation intended to misrepresent the results," it did list a litany of errors within the paper—of which most had been addressed in the Citizen's Petition:

- The commercial catalog number listed for the primary antibody against α7 nicotinic receptor is incorrect.
- The specific activity of the C^{14}-PTI-125 is incorrect.
- The filamin A (FLNA) concentration in the binding assay is incorrect.
- The scintillation counter used to assay C^{14} was not properly calibrated or configured for the C^{14} radioisotope, and the absolute values reported are not reliable.
- In Figure 7, the 10-month-old HP panel for the WT – PTI-125 group is duplicated as the 6-month-old HP panel for the WT – vehicle group.
- Labeling in the key to Figure 12, lane 8, is incorrect.
- NR1 loading controls in Figure 12 were not measured from stripped re-probed gels as indicated in the published report; they were run on separate gels and one lane was omitted in Figure 12.

- Whereas the composition of Figure 12 suggests that all conditions were run on the same gel, conditions were in fact split across two gels (without internal controls or repeats).

390. Regarding Figure 7, as addressed in the Expression of Concern's fifth bullet point, while the journal did not find it was enough evidence, the manipulation of Figure 7 still reflects deliberate data manipulation. Based on the image below, it is clear that such alteration could not have happened by accident—it required intent.



391. As the Expression of Concern makes clear, it "is aware of an ongoing inquiry of these and other concerns by the sponsoring institution, [CUNY], and will make a final decision as to appropriate corrective action once that inquiry has been concluded."

March 24, 2022 Proxy Statement

392. On March 24, 2021, Cassava filed the 2022 Proxy Statement with the SEC. Defendants Barbier, Gussin, O'Donnell, Robertson, and Scannon and Dr. Friedmann solicited the

2022 Proxy Statement filed pursuant to Section 14(a) of the Exchange Act, which contained material misstatements and omissions.[15]

393. The 2022 Proxy Statement called for Company shareholders to, *inter alia*: (1) re-elect Dr. Friedmann and Defendant O'Donnell to the Board; (2) approve an amendment to the 2018 Plan to add an additional 4 million shares to the 2018 Plan for issuance to Company employees, directors, and consultants; (3) to ratify Ernst & Young LLP as the Company's independent auditor for the fiscal year ending December 31, 2022; and (4) approve, by a non-binding advisory vote, the 2021 executive compensation for the Company's named executive officers, namely Dr. Friedmann and Defendants Barbier, Kupiec, and Schoen.

394. The 2022 Proxy Statement stated the following regarding the Board's risk oversight functions:

> One of the key functions of the Board of Directors is informed oversight of the risk management process. The Board administers this oversight function directly through the Board of Directors as a whole, as well as through its standing committees that address risks inherent in their respective areas of oversight. Areas of focus include economic, operational, financial (accounting, credit, investment, liquidity and tax), competitive, legal, regulatory, cybersecurity, privacy, compliance and reputational risks, and more recently, risk exposures related to COVID-19. The risk oversight responsibility of the Board of Directors and its committees is supported by the management reporting processes, which are designed to provide visibility to the Board of Directors and to the personnel who are responsible for risk assessment and information about the identification, assessment and management of critical risks, and management's risk mitigation strategies.
>
> The Audit Committee is responsible for reviewing and discussing major financial risk exposures and the steps management has taken to monitor and control these exposures, including guidelines and policies with respect to risk assessment and risk management. The Audit Committee also monitors compliance with legal and

[15] Plaintiff's allegations with respect to the misleading statements in the 2022 Proxy Statement are based solely on negligence; they are not based on any allegation of reckless or knowing conduct by or on behalf of the Individual Defendants, and they do not allege, and do not sound in, fraud. Plaintiff specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to these allegations and related claims.

> regulatory requirements and assists the Board of Directors in fulfilling its oversight responsibilities with respect to risk management. The Compensation Committee assesses and monitors whether any of the compensation policies and programs has the potential to encourage excessive risk-taking.
>
> The Company believes this division of responsibilities is an effective approach for addressing the risks the Company faces and that the board leadership structure supports this approach.

(Emphasis added.)

395. The 2022 Proxy Statement contained the following description of the Audit Committee:

> The Audit Committee consists of directors Mr. Barry, who is the chair of the Audit Committee, Dr. Gussin and Mr. Robertson. Dr. Scannon served as a member of the Audit Committee in 2021 until the appointment of Mr. Barry to the Board of Directors in June 2021. The Board of Directors of the Company has determined that each member of the Audit Committee is financially literate. In addition, the Board of Directors has determined that the composition of the Audit Committee meets the requirements for independence under current Nasdaq Stock Market LLC listing standards and SEC rules. The Board of Directors has also determined that Mr. Robertson is an "audit committee financial expert" as defined in the SEC rules. The Audit Committee operates under a written charter adopted by the Board of Directors. The Company maintains a copy of the Audit Committee charter on its website: www.cassavasciences.com. The Audit Committee reviews the Company's internal accounting procedures, consults with and reviews the services provided by the Company's independent registered public accounting firm and makes recommendations to the Board of Directors regarding the selection of the independent registered public accounting firm. The Audit Committee held four meetings during fiscal year 2021.

396. The 2022 Proxy Statement contained the following description of the Compensation Committee:

> The Compensation Committee consists of directors Dr. Gussin and Mr. Robertson. The Board of Directors of the Company has determined that these individuals are independent as defined under the Nasdaq Stock Market LLC listing standards. The Compensation Committee reviews and recommends to the Board of Directors the salaries, incentive compensation and benefits of the Company's officers and administers the Company's stock plans and employee benefit plans. Refer to the section entitled "Compensation Discussion and Analysis" for more information about the Company's Compensation Committee and its processes and procedures. The Compensation Committee operates under a written charter adopted

> by the Board of Directors. The Company maintains a copy of the Compensation Committee charter on its website: www.cassavasciences.com. The Compensation Committee held two meetings during fiscal year 2021.

397. The 2022 Proxy Statement noted that "of the 1,000,000 shares of Common Stock originally authorized under the 2018 Plan, after all award grants made by the Compensation Committee of our Board of Directors (the "Compensation Committee"), 151,188 shares remained available for grant as of March 15, 2022.

398. The 2022 Proxy Statement was materially misleading because it failed to disclose that: (1) contrary to the 2022 Proxy Statement's descriptions of the Board's risk oversight function and the Audit Committee's responsibilities, the Board and its committees were not adequately exercising these functions, were causing or permitting the Company to submit manipulated data to the FDA and to issue false and misleading statements to the investing public, and thus the Individual Defendants on the Board were breaching their fiduciary duties; and (2) the Individual Defendants on the Board who were breaching their fiduciary duties were improperly interested in increasing their unjust compensation by seeking shareholder approval of the amendment to the 2018 Plan, which the Individual Defendants serving on the Compensation Committee were improperly administering by rewarding misconduct.

399. The 2022 Proxy Statement also failed to disclose that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy were overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show that simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had been sent not to an outside lab, as the Company represented,

but rather to Dr. Wang, who is a paid consultant of Cassava, a member of Cassava's scientific advisory board, and an individual who receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements were materially false and misleading at all relevant times.

400. As a result of the material misstatements and omissions contained in the 2022 Proxy Statement, Company shareholders approved the amendment to the 2018 plan; reelected Dr. Friedmann and Defendant O'Donnell to the Board, allowing them to continue breaching their fiduciary duties to Cassava; ratified Ernst & Young LLP as independent auditor, and approved, on a nonbinding advisory basis, the 2021 compensation of Dr. Friedmann and Defendants Barbier, Kupiec, and Schoen.

March 29, 2022 Neuroscience "Corrigendum"

401. On March 29, 2022, the journal *Neuroscience* announced that Dr. Wang had provided a "corrigendum," admitting to errors Dr. Bik had pointed out in his article "Stress Diminishes BDNF-stimulated TrkB Signaling, TrkB-NMDA Receptor Linkage and Neuronal Activity in the Rat Brain." The corrigendum stated:

> The authors regret that ***two errors pertaining to the visual display of representative western blot images were made during the generation of Fig. 4A and Fig. 7***. In Fig. 4A, an incorrect image of six protein bands was inserted instead of the correct Erk2 band (lower band). In Fig. 7A, the β-actin bands was placed in the incorrect orientation (bottom band).

402. Dr. Bik, however, saw greater cause for concern. In her opinion, "[t]he uncropped blots in the correction do not appear to be uncropped blots." A month later, Dr. Bik raised more concerns stating, "the molecular weight sizes of the proteins on the 'uncropped' blots provided for Figures 4 and 7 also do not seem to match that of the individual blot panels shown in the publication." Dr. Bik furthered that "[t]he uncropped blot for Figure 4A shows PSD95 (100 kDa), pAkt1 (55kDa), and ERK2 (55 kDa). The pAkt1 and ERK2 bands should run at the same size, but they are shown far apart." Additionally, "[t]he uncropped blot for Figure 7A shows TrkB (130 kDa, Akt1 (55 kDa), and b-Actin (55 kDa). The Akt1 and b-Actin bands should run at the same size, but they are shown far apart."

March 30, 2022 PLOS One Retractions

403. On March 30, 2022, the journal *PLOS One* announced it was retracting five papers published by Drs. Wang and Burns. Of the papers were two seminal publications, their 2008 paper "High-Affinity Naloxone Binding to Filamin A prevents Mu Opioid Receptor-Gs Coupling Underlying Opioid Tolerance and Dependence" (the "2008 Paper") and their 2009 paper titled "Naloxone's Pentapeptide Binding Site on Filamin A Blocks Mu Opioid Receptor-Gs Coupling and CREB Activation of Acute Morphine" (the "2009 Paper"). *PLOS One* stated that "[t]he data and comments provided to *PLOS ONE* ***did not resolve the concerns about the integrity and reliability of the reported data***. In light of these issues, the *PLOS ONE* Editors retract this article."

404. In the retraction for the 2008 Paper, *PLOS One* stated the following, in relevant part:

> ***The corresponding author provided image data to support the contested western blot results in this [1] and other PLOS ONE articles [2–5].*** Per PLOS' assessment of the data files, the pixel patterns in background areas of blot images provided for multiple panels in [1–5] appear more similar than would be expected for data obtained in independent experiments. Furthermore, the supporting data files did not contain positive controls as needed to verify the reliability of the results. In response

> to these concerns, the corresponding author stated that the repetitive features in the background noise of the image data are likely the result of scanner artifacts. ***The explanation given for the background image similarities does not resolve the journal's concerns in light of PLOS' assessment of the data files.***
>
> ***The data and comments provided did not resolve the concerns about the integrity and reliability of data presented in this article. In light of these issues, the PLOS ONE Editors retract this article.***
>
> HYW and LB did not agree with the retraction. MF either did not respond directly or could not be reached. HYW stands by the article's findings.

(Emphasis added.)

April 18, 2022 New York Times Exposé

405. On April 18, 2022, the *New York Times* published an article titled "Scientists Question Data Behind an Experimental Alzheimer's Drug," gathering expert opinions by scientists in the field and detailed their suspicions regarding Cassava's findings and methods. During the course of the investigation, "[t]he New York Times contacted nine prominent experts for comment about the scientific underpinnings of Cassava's trials. ***All said they did not trust the company's methods, results or even the premise underlying the drug's supposed effectiveness***." (Emphasis added.)

406. The litany of experts continued to critique the Company's claims regarding simufilam. Dr. Thomas Südhof, a Nobel laureate, stated that Cassava's "conclusions with regard to Alzheimer's disease make no sense to me whatsoever." Dr. Südhof also directed his suspicion to the fact that these theories "are no in the mainstream of the field…." Dr. Lawrence Honig, an Alzheimer's disease expert at Columbia, added that "[a]ll the evidence [that supports the theory] seems to be from [Dr. Wang's lab]."

407. Similarly, Dr. Roger Nicoll, a Neurologist at U.C. San Fransico, stated "[t]his drug should not be put into patients. It should never have been. Never… The longer this goes on, the more outraged I am."

408. Dr. Roger Howard of University College London critiqued Cassava's data because its study "did not compare the medication to a mock treatment or placebo… [a]ll of the participants in this trial received the drug and were aware of it." Dr. Howard furthered that Cassava's findings would be miraculous because it indicates "reversing neurodegeneration," while for every other drug in the field simply "slowing or stopping… cognitive decline" is seen as a win. Dr. Howard concluded that "to claim that patients are actually improving on the basis of smalls numbers, 'at the very least is implausible.'"

409. Dr. George Perry, a neuroscientist at the University of Texas at San Antonio and the editor in chief of *The Journal of Alzheimer's Disease*, emphasized that "[if] the data is suspect in key papers, and not just minor mistakes, you can't trust anything…. It'll have to be independently validated."

410. Dr. William Hu, "an expert on spinal fluid markers at Rutgers," had more pointed criticism of the Company's suspect data. In Dr. Hu's opinion, "There's a clear discrepancy there for those of us who work with C.S.F. biomarkers…. ***That type of discrepancy really raises questions in terms of the rigor as well as the reliability of these results***." (Emphasis added.) This is critical because the Company has "pointed to changes in the levels of certain molecules in [C.S.F.] as evidence of simufilam's effectiveness."

411. Drs. Honig and Bik critiqued the Company's use of Western blotting as the foundational method of proof. In Dr. Honig's opinion, Western blotting lacks "the sensitivity or reproducibility or accuracy" found in new methods. Dr. Bik emphasized an opinion consistent with her other works, noting that "it is highly likely that there was some [data] manipulation going on[]" in Drs. Wang's and Burns' Western blots.

412. While Dr. Charles Spruck, a cancer researcher in San Diego with 25 years of experience using the Western blot method, noted that any anomalies could be because of "simple mistakes or vagaries of the technique," Dr. David Vaux, deputy director of scientific integrity and ethics at the Walter Eliza Hall Institute of Medical Research, is less convinced. In Dr. Vaux's opinion, "when you see [irregularities or errors] again and again, it makes it unlikely that you could do it accidentally[.]"

413. The *New York Times* noted that Dr. Vaux, and other experts, "bemoaned the limitations of peer review in identifying mistakes or manipulation, and said many scientific journals are reluctant to retract papers because of their fear of being sued, or damage to their own reputations."

414. Defendant Barbier, however, described all critics as "bad actors," driven by taking short positions on Cassava. Defendant Barbier stated "They have gone, and continue to go, to unreal extremes to halt our progress…. The effort to besmirch Cassava Sciences appears endless." Regarding consistent irregularities in the Company's Western blot data, Defendant Barbier stated, in contrast to the litany of experts, that "[t]hese background pixels have no impact on the data or its interpretation[.]"

415. On this news, the Company's stock price fell from $22.46 per share at the closing of trade on April 19, 2022, to $20.39 per share at the closing of trade on April 20, 2022. This represented an 11.3% decrease in price per share, or a drop of $4.92.

June 1, 2022 Alzheimer's Research & Therapy Retraction

416. On June 1, 2022, *Alzheimer's Research & Therapy* retracted Dr. Wang's 2017 paper titled "Increased Aβ42-α7-like nicotinic acetylcholine receptor complex level in lymphocytes is associated with apolipoprotein E4-driven Alzheimer's disease pathogenesis."

417. The retraction note read:

> The Editors-in-Chief have retracted this article. Following publication, concerns have been raised regarding the western blot images presented in Figs. 1, 5 and 6. The authors have provided the raw data, which have been assessed by independent experts and deemed insufficient to address the concerns. The Editors-in-Chief therefore no longer have confidence in the integrity of the data in this article.

418. While five of the authors agreed to the retraction, Dr. Wang and three others did "not agree to this retraction."

419. On this news, Cassava's stock price fell from $30.60 per share at the closing of trade on May 31, 2022, to $26.82 per share at the closing of trade on June 1, 2022.

July 27, 2022 Reuters Article

420. On July 27, 2022, *Reuters* published "Exclusive: Cassava Sciences faces U.S. criminal probe tied to Alzheimer's drug, sources say." The story noted that the DOJ "opened a criminal investigation into [Cassava] involving whether the biotech company manipulated research results for its experimental Alzheimer's drug[.]" The article revealed that the personnel "conducting the investigation into [Cassava] specialize in examining whether companies or individuals have misled or defrauded investors, government agencies or consumers[.]"

421. On this news, the Company's stock price fell from $21.72 per share at the closing of trade on July 26, 2022, to $18.69 per share at the closing of trade on July 27, 2022. This represented a drop of 14% of share value or $3.03 per share.

422. The Individual Defendants and as a collective Board were well aware that disclosing the Company had been under criminal investigation since November 2021 would have materially impacted the mix of information available to investors. The materiality of the Board's omission is reflected in the stock drop that followed the *Reuters* revelation that the investigation was criminal.

October 12, 2023 Science Article

423. On October 12, 2023, the journal *Science* published an article entitled *Co-Developer of Cassava's Potential Alzheimer's Drug Cited for 'Egregious Misconduct*.' The article reported that:

> A much-anticipated investigation by the City University of New York has accused neuroscientist Hoau-Yan Wang, a CUNY faculty member and longtime Cassava collaborator, of scientific misconduct involving 20 research papers. Many provided key support for simufilam's jump from the lab into clinical studies and, given the CUNY report, some scientists are now calling for the two ongoing trials to be suspended….
>
> It also concluded that Lindsay Burns, Cassava's senior vice president for neuroscience and a co-author on several of the papers, bears primary or partial responsibility for some of the possible misconduct or scientific errors.

424. As reported in *Science*, the CUNY committee conducting the investigation noted that Dr. Wang "failed to turn over to the panel 'even a single datum or notebook in response to any allegation' and cites 'Wang's inability or unwillingness to provide primary research materials to [the] investigation[.]"

The Individual Defendants' Knowledge of the Misconduct

425. The Individual Defendants knew, or were reckless in not knowing, that the Company was utilizing manipulated data and making false and misleading statements about the efficacy of simufilam and the research process. Following the failure of Remoxy, simufilam was the Company's *sole focus.*

426. The September 14, 2020 Press Release announced the highly anticipated Phase 2b results, represented Dr. Wang's lab as an "outside lab," even though he was a beneficiary of the Company's stock plan, was on Cassava's Scientific Advisory Board, and it was his lab at CUNY who was conducting the Phase 2b reanalysis. Defendants Barbier, Robertson, O'Donnell, Gussin,

and Scannon would then sign the 2020 10-K falsely representing that Phase 2b was reconducted by an outside lab.

427. Additionally, many of the Directors hold specialized knowledge that should have or did make them acutely aware of the fact that the research contained manipulated data. Defendant Gussin holds a PhD, serves on advisory boards at Duquesne University Pharmacy School and the University of Michigan Medical School, and has worked in the drug development business since starting at Johnson and Johnson in 1986. Similarly, Defendant Scannon is the founder of his own biotechnology company, Xoma Corp., where he served as the Chief Scientific and Medical Officer, and he holds an M.D. from the Medical College of Georgia and a Ph.D. in Organic Chemistry from the University of California Berkely. Accordingly, both of these Defendants hold specialized knowledge that made them aware or should have made them aware of the research improprieties littered throughout Cassava's publications.

428. Regarding research misconduct allegations and omitting the severity of government investigations from shareholders, all Director Defendants (defined below) were well aware and consistently approved false and misleading statements that enable these falsehoods and omissions to perpetuate. Further, they failed to correct Defendant Barbier's false and misleading statements on behalf of the Company that stated the misrepresented data was an immaterial mistake.

429. Despite the litany of Government investigations into the Company that should have put the Board on notice, they allowed or failed to correct the Company's omittance of the severity of these investigations. Yet, no one in the Company disclosed such fact until the *Reuters* article on July 27, 2022, forced the Company to come clean. Accordingly, Defendants knew that the Company was omitting material information from investors and yet either acquiesced or actively caused the Company to omit this material information.

Post Relevant Period Events

March 13, 2023 Form 8-K

430. In a Form 8-K filed with the SEC on March 13, 2023, Cassava announced that non-employee directors were no longer entitled to bonus compensation under the Plan. The Company announced it was removing non-employee directors from the Plan as a result of shareholder derivative actions using Plan benefits to prove unjust enrichment and breaches of fiduciary duty. Accordingly, "non-employee directors' share of potential benefits under the Cash Incentive Plan were completely forfeited to the Company and will not be allocated to any other participant under the Cash Incentive Plan."

431. Defendants Barbier, Schoen, and Kupiec are still entitled to substantial bonus awards provided under the Plan.

May 5, 2023 Securities Class Action Motion to Dismiss

432. On May 5, 2023, this Court issued its decision on the Defendants' Motion to Dismiss the Consolidated Securities Class Action. ECF 104. In that decision, this Court upheld all of the Plaintiff's claims, except those against the deceased Dr. Friedmann pursuant to F.R.C.P 25(a)(1). (ECF 104, at 32).

433. This Court held that the "Plaintiffs have sufficiently pled actionable misstatements and omissions by Defendants" regarding claims related to:

- The Phase 2a study and 2b reanalysis "suffered from highly anomalous baseline measurements."
- Defendants "intentionally removed unfavorable data" from Cassava's presentation of the Phase 2b results.
- The Phase 2b reanalysis was conducted by Dr. Wang's lab.
- Quanterix did not interpret the test results or prepare the data for the Phase 2b reanalysis.
- The missing data point from the AAIC poster reflected a 150% increase rather than a 38% increase.

(*Id.* at 20, 18) (citations omitted). In the opinion of this Court, a "reasonable investor could certainly have viewed these omissions—particularly the omission related to the involvement of Dr. Wang's lab—as significantly altering the total mix of information available." (*Id.* at 18).

434. This Court further acknowledged that the Securities Class Action plaintiffs' claims that Defendants touted simufilam research while failing to disclose it was "rife with manipulated data," is actionable. (*Id.* at 19). This is because if ultimately proven true that Cassava had manipulated data and information, then any statement the Company or Individual Defendants made regarding the research of simufilam would be false and misleading. (*Id*). Notably, both our action and the Securities Class Action supports its claims *not just* with the revelation that the DOJ and NIH have opened up investigations into Cassava, *but also* with both photographic evidence of data manipulation and a litany of support by experts in the field. (*Id.*)

435. Additionally, the Court held that the materiality of these omissions regarding data manipulation are strongly support by the stock drops that "accompanied each revelation of an alleged omission or misrepresentation." (*Id*, at 20).

436. Regarding specific allegations of scienter, this Court found that plaintiffs in the Securities Class Action supported their allegations by demonstrating (1) Cassava engaged in "selective reporting" (i.e., not revealing that "the outside lab" was actually Dr. Wang's lab); (2) the reaction of the scientific community to the revelations of Cassava's "apparent extreme manipulations"; and (3) the immediacy of Defendant Barbier's and Cassava's rejection of the Citizens Petition claims demonstrates the Defendants were either "sufficiently familiar with the facts, or severely reckless in not being familiar, to be in a position to issue a denial." (*Id*., at 23-24).

437. Regarding the Defendants' motive, this Court upheld the Securities Class Action's reliance on the Board's institution of the new cash bonus plan, which had tied executive compensation and Company financing to the Company's stock price, as a basis to infer scienter. (ECF 104, at 24). The Court agreed with the plaintiffs that, even though the Company never paid out the hundreds of millions in dollars that had been promised under the plan, the bonus plan nonetheless "allowed Defendants to profit regardless of the long-term value of Cassava's stock price." (*Id.*, at 24-25). For example, Barbier earned close to $27 million in salary, bonuses, and stock options as CEO of Pain Therapeutics, even though Pain Therapeutics had lost nearly 98% of its stock value. (*Id.*, at 25). The Court noted that the timing and the structure of the bonus plan show motive. (*Id.*)

438. Additionally, this Court believed that the ability to raise essential capital through artificially inflating the stock price "can be probative of scienter." (*Id.*) Notably, the Defendants engaged in two stock shares to raise capital following the artificial inflation of the Company's stock both in October 2021 and February 2022.

439. Finally, this Court found sufficient evidence to support an inference of scienter to all Defendants in the Securities Class Action, including Defendants Barbier, Burns, and Schoen. (*Id.*, at 27). Regarding Defendant Barbier: (1) he was an author of the (allegedly manipulated) 2020 paper regarding the 2a study results; (2) is CEO of the "small company, with only eight or nine employees in 2019 and eleven in 2020"; (3) is married to Defendant Burns, the Company's head researcher of simufilam; and (4) he ultimately has "global responsibilities for the scientific direction, management, operations, strategy, and financing of the Company." (ECF 104, at 27).

440. Regarding Defendant Burns, this Court stated that she: (1) serves as the SVP of Neuroscience; (2) is married to Defendant Barbier, the CEO of the Company; (3) co-authored the

controversial 2020 paper and gave presentations "alleged to contain manipulated data"; and (4) was responsible for "monitor[ing] the proof-of-concept research, lead selection and efficacy experiments for [simufilam] and over[seeing] IND-enabling studies, chronic toxicity studies, and first-in-human and first-in-patient clinical trials." (*Id.*, at 27-28).

441. Regarding Defendant Schoen, while the Court found these allegations to be the weakest, it still upheld allegations against him. In particular, scienter was supported by: (1) the Company's failure to disclose that Dr. Wang's lab was the purported "outside lab"; (2) Schoen signing the Form 8-K with an attached press release announcing the Phase 2b "final results"; and (3) Schoen's participation in the cash bonus plan. (*Id.*, at 28-29).

DAMAGES TO CASSAVA

442. As a direct and proximate result of the Individual Defendants' misconduct, Cassava has lost and will continue to lose and expend many millions of dollars.

443. Such expenditures include, but are not limited to, the fees associated with the Securities Class Action filed against the Company and various of the Individual Defendants, and any internal investigations, and amounts paid to outside lawyers, accountants, and investigators in connection thereto.

444. Such expenditures also include, but are not limited to, the costs incurred by the Company in undertaking any remedial measures in connection to it submitting manipulated data to the FDA.

445. Additionally, these expenditures include, but are not limited to, unjust compensation, benefits, and other payments provided to the Individual Defendants who breached their fiduciary duties to the Company.

446. As a direct and proximate result of the Individual Defendants' conduct, Cassava has also suffered and will continue to suffer a loss of reputation and goodwill, and a "liar's discount" that will plague the Company's stock in the future due to the Company's and their misrepresentations and the Individual Defendants' breaches of fiduciary duties and unjust enrichment.

DERIVATIVE ALLEGATIONS

447. Plaintiff brings this action derivatively and for the benefit of Cassava to redress injuries suffered, and to be suffered, as a result of the Individual Defendants' breaches of their fiduciary duties as directors and/or officers of Cassava, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, violations of the Exchange Act, and the aiding and abetting thereof.

448. Cassava is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

449. Plaintiff is, and has been at all relevant times, a shareholder of Cassava. Plaintiff will adequately and fairly represent the interests of Cassava in enforcing and prosecuting its rights, and, to that end, has retained competent counsel, experienced in derivative litigation, to enforce and prosecute this action.

DEMAND FUTILITY ALLEGATIONS

450. Plaintiff incorporates by reference and realleges each and every allegation stated above as if fully set forth herein.

451. A pre-suit demand on the Board of Cassava is futile and, therefore, excused. At the time of filing of this action, the Board consisted of the following six individuals: Defendants Barbier, Barry, Gussin, O'Donnell, Robertson, and Scannon (the "Director Defendants"). Plaintiff

needs only to allege demand futility as to three of six Directors who are on the Board at the time this action is commenced.

452. Demand is excused as to all of the Director-Defendants because each one of them faces, individually and collectively, a substantial likelihood of liability as a result of the scheme they engaged in knowingly or recklessly to cause the Company to submit manipulated data to the FDA and to make and/or cause the Company to make false and misleading statements and omissions of material facts, which renders them unable to impartially investigate the charges and decide whether to pursue action against themselves and the other perpetrators of the scheme.

453. In complete abdication of their fiduciary duties, the Director-Defendants either knowingly or recklessly participated in the foregoing scheme. The fraudulent scheme was intended to make the Company appear more profitable and attractive to investors, with the Director-Defendants conducting a $200 million stock offering at artificially inflated prices during the Relevant Period. Moreover, the Director-Defendants caused the Company to fail to maintain internal controls. As a result of the foregoing, the Director-Defendants breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile, and thus excused.

454. Additional reasons that demand on Defendant Barbier is futile follow. Defendant Barbier has served as the Company's CEO, President, and Chairman of the Board since he founded the Company in May 1998. Thus, as the Company admits, he is a non-independent director. The Company provides Defendant Barbier with his principal occupation for which he receives substantial compensation. As CEO and President, Defendant Barbier was ultimately responsible for all of the false and misleading statements and omissions that were made during the Relevant Period, including the statements he personally made in numerous press releases during the

Relevant Period and the statements in the 2020 10-K, which he signed and signed SOX certifications. In addition, the 2021 Proxy Statement was solicited on his behalf, and the false and misleading statements contained therein contributed to his reelection to the Board and shareholders approving, on an advisory basis, his unjust compensation. Moreover, the 2022 Proxy Statement was solicited on his behalf, and the false and misleading statements contained therein contributed to the reelection of Defendant O'Donnell and shareholders approving, on an advisory basis, his unjust compensation. As the Company's highest officer and as trusted Chairman of the Board, he conducted little, if any, oversight of the scheme to cause the Company to submit manipulated data to the FDA and to make false and misleading statements, consciously disregarded his duties to monitor internal controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Moreover, Defendant Barbier is a defendant in the Securities Class Action. For these reasons, Defendant Barbier breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

455. Additional reasons that demand on Defendant Barry is futile follow. Defendant Barry has served as a Company director since June 2021. He also serves as the chair of both the Nominating & Governance Committee and the Audit Committee. The 2022 Proxy Statement, which contained false and misleading statements, was solicited on his behalf. As a trusted Company director, he conducted inadequate, if any, oversight of the Company's controls, allowing the scheme to cause the Company to submit manipulated data to the FDA to be perpetuated and the Company to make false and misleading statements, consciously disregarded his duties to monitor internal controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. For these reasons, Defendant Barry breached his

fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile.

456. Additional reasons that demand on Defendant Gussin is futile follow. Defendant Gussin has served as a Company director since March 2003. He also serves as a member of both the Audit Committee and the Compensation Committee. Defendant Gussin signed, and thus personally made, the false and misleading statements contained in the 2020 10-K. Moreover, the 2021 Proxy Statement and 2022 Proxy Statement, both of which contained false and misleading statements, were solicited on his behalf. As a trusted Company director, he conducted inadequate, if any, oversight of the Company's controls, allowing the scheme to cause the Company to submit manipulated data to the FDA to be perpetuated and the Company to make false and misleading statements, consciously disregarded his duties to monitor internal controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. For these reasons, Defendant Gussin breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

457. Additional reasons that demand on Defendant O'Donnell is futile follow. Defendant O'Donnell has served as a Company director since June 1998. Defendant O'Donnell signed, and thus personally made, the false and misleading statements contained in the 2020 10-K. Moreover, the 2021 Proxy Statement and 2022 Proxy Statement, both of which contained false and misleading statements, were solicited on his behalf. As a trusted Company director, he conducted inadequate, if any, oversight of the Company's controls, allowing the scheme to cause the Company to submit manipulated data to the FDA to be perpetuated and the Company to make false and misleading statements, consciously disregarded his duties to monitor internal controls

over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. For these reasons, Defendant O'Donnell breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

458. Additional reasons that demand on Defendant Robertson is futile follow. Defendant Robertson has served as a Company director since September 1998. He also serves as a member on each of the Audit Committee, the Compensation Committee, and Nominating and Governance Committee. In addition, he serves as Lead Director. Defendant Robertson signed, and thus personally made, the false and misleading statements contained in the 2020 10-K. Moreover, the 2021 Proxy Statement and 2022 Proxy Statement were solicited on his behalf and the false and misleading statements contained therein contributed to his reelection to the Board. As a trusted Company director, he conducted inadequate, if any, oversight of the Company's internal controls, allowing the scheme to cause the Company to submit manipulated data to the FDA to be perpetuated and the Company to make false and misleading statements, consciously disregarded his duties to monitor internal controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. For these reasons, Defendant Robertson breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

459. Additional reasons that demand on Defendant Scannon is futile follow. Defendant Scannon has served as a Company director since December 2007. During the Relevant Period, he served as a member of the Audit Committee. Defendant Scannon signed, and thus personally made, the false and misleading statements contained in the 2020 10-K. Moreover, the 2021 Proxy Statement and 2022 Proxy Statement were solicited on his behalf and the false and misleading

statements contained therein contributed to his reelection to the Board. As a trusted Company director, he conducted inadequate, if any, oversight of the Company's controls, allowing the scheme to cause the Company to submit manipulated data to the FDA to be perpetuated and the Company to make false and misleading statements, consciously disregarded his duties to monitor internal controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. For these reasons, Defendant Scannon breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

460. Additional reasons that demand on the Board is futile follow.

461. The Director Defendants have longstanding business and personal relationships with each other and the Individual Defendants that preclude them from acting independently and in the best interests of the Company and the shareholders. For example, Dr. Friedmann and Defendants Scannon have prior experience working together from their overlapping time at XOMA Corporation, which Defendant Scannon founded. Moreover, Dr. Friedmann also worked together with Defendant Gussin at Johnson & Johnson. In addition, Defendants Barbier, O'Donnell, and Robertson, have worked together at the Company for over two decades since they all joined in 1998, with Defendant Gussin working with them for almost that long having joined in 2003. Defendants Scannon and Marsman have also worked with Dr. Friedmann and Defendants Barbier, O'Donnell, Robertson, and Gussin at the Company for over a decade, with Defendant Scannon joining in 2007 and Defendant Marsman working at the Company for neatly ten years before leaving in 2012 but then rejoining in 2015. Additionally, Defendant Barbier is married to Defendant Burns, the lead scientist in the development of simufilam. These conflicts of interest precluded the Director Defendants from adequately monitoring the Company's operations and

internal controls and calling into question the Individual Defendants' conduct. Thus, demand upon the Director Defendants would be futile.

462. Defendants Barry, Gussin, Robertson, and Scannon (the "Audit Committee Defendants") served as members of the Audit Committee during the Relevant Period. Pursuant to the Company's Audit Committee Charter, the Audit Committee Defendants are responsible for, *inter alia*, monitoring the Company's system of internal controls, reviewing their adequacy on an ongoing basis, and recommending to the Board remedies to any identified deficiencies. The Audit Committee Defendants failed to adequately oversee the Company's internal controls, failed to identify or remedy deficiencies with the Company's internal controls, and thus failed prevent the Company from issuing false and misleading statements to the public and the SEC. Thus, the Audit Committee Defendants breached their fiduciary duties, are not disinterested, and demand is excused as to them.

463. Defendants Gussin and Robertson (the "Compensation Committee Defendants") served as members of the Compensation Committee during the Relevant Period. As stated in the 2021 Proxy Statement, "[t]he Compensation Committee reviews and recommends to the Board of Directors the salaries, incentive compensation and benefits of the Company's officers and administers the Company's stock plans and employee benefit plans." The Compensation Committee Defendants thus reviewed and recommended to the Board the salaries, incentive compensation and benefits of the Individual Defendants, and awarded them compensation under the Company's stock plans. This compensation was unjust in light of the Individual Defendants'—including the Compensation Committee Defendants'—violations of law. Thus, the Compensation Committee Defendants breached their fiduciary duties, are not disinterested, and demand is excused as to them.

464. Additional reasons why demand is futile to all Director Defendants follows. Prior to the March 17, 2023, announcement that non-employee directors would no longer be entitled to bonus compensation under the Plan, Director Defendants were under the impression for the entirety of the Relevant Period that they had the potential to earn massive bonuses. As of the 2022 Proxy Statement, the Defendants stood to share "a minimum of $81.0 million up to a hypothetical maximum of $195.0 million." While the non-employee Directors are no longer entitled to their share, for the entirety of the Relevant Period and at the time that this action was commenced, the Director Defendants were incentivized to be a part of the schemes as a result of lucrative bonuses. The only reason these Defendants have lost their entitlements is to retroactively defend claims that they breached their Fiduciary Duties. Unfortunately for the Director Defendants, relenting their compensation packages in 2023 does not mitigate the substantial reputational damage they caused the Company when they engaged in the scheme to facilitate false and misleading statements to artificially inflate the stock price. Accordingly, the Plan represented the Defendants incentive in facilitating the scheme and the Board's full coordination in both passing and, subsequently, repealing the Plan demonstrates why demand is futile.

465. In violation of the Code of Ethics, the Director Defendants conducted inadequate, if any, oversight of the Company's internal controls, allowing its engagement in the Individual Defendants' scheme to cause the Company to submit manipulated data to the FDA and to issue materially false and misleading statements to the public and to facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, gross mismanagement, abuse of control, waste of corporate assets, unjust enrichment, and violations of the Exchange Act. In further violation of the Code of Ethics, the Director-Defendants failed to act with honesty and integrity; failed to provide the SEC and public with complete, fair, accurate, timely, and

understandable disclosures; failed to comply with applicable laws and regulations; failed to act in good faith, responsibly with due care and diligence and without misrepresentation or omission of material facts; failed to promote ethical behavior at the Company; and failed to promptly report violations of the Code of Ethics. Thus, the Director-Defendants face a substantial likelihood of liability and demand is futile as to them.

466. Cassava has been and will continue to be exposed to significant losses due to the wrongdoing complained of herein, yet the Directors have not filed any lawsuits against the Individual Defendants or others who were responsible for that wrongful conduct to attempt to recover for Cassava any part of the damages Cassava suffered and will continue to suffer thereby. Thus, any demand upon the Directors would be futile.

467. The Individual Defendants' conduct described herein and summarized above could not have been the product of legitimate business judgment as it was based on bad faith and intentional, reckless, or disloyal misconduct. Thus, none of the Director-Defendants can claim exculpation from their violations of duty pursuant to the Company's charter (to the extent such a provision exists). As a majority of the Directors face a substantial likelihood of liability, they are self-interested in the transactions challenged herein and cannot be presumed to be capable of exercising independent and disinterested judgment about whether to pursue this action on behalf of the shareholders of the Company. Accordingly, demand is excused as being futile.

468. The acts complained of herein constitute violations of fiduciary duties owed by Cassava's officers and directors, and these acts are incapable of ratification.

469. The Director Defendants may also be protected against personal liability for their acts of mismanagement and breaches of fiduciary duty alleged herein by directors' and officers' liability insurance if they caused the Company to purchase it for their protection with corporate

funds, i.e., monies belonging to the stockholders of Cassava. If there is a directors' and officers' liability insurance policy covering the Directors, it may contain provisions that eliminate coverage for any action brought directly by the Company against the Directors, known as, *inter alia*, the "insured-versus-insured exclusion." As a result, if the Board in place at the time this action was commenced were to sue the Director Defendants or certain of the officers of Cassava, there would be no directors' and officers' insurance protection. Accordingly, the Demand Board cannot be expected to bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage, if such an insurance policy exists, will provide a basis for the Company to effectuate a recovery. Thus, demand on the Directors is futile and, therefore, excused.

470. If there is no directors' and officers' liability insurance, then the Demand Board will not cause Cassava to sue the Individual Defendants named herein, since, if they did, they would face a large uninsured individual liability. Accordingly, demand is futile in that event, as well.

471. Thus, for all of the reasons set forth above, at least half of the Demand Board cannot consider a demand with disinterestedness and independence. Consequently, demand is excused as futile.

FIRST CLAIM

Against the Director-Defendants for Violations of Section 14(a) of the Exchange Act

472. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

473. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that "[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of

such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C. § 78l]."

474. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain "any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading." 17 C.F.R. § 240.14a-9.

475. Under the direction and watch of the Director Defendants (except Defendant Barry), the 2021 Proxy Statement failed to disclose, *inter alia*: (1) contrary to the 2021 Proxy Statement's and the 2022 Proxy Statement's descriptions of the Board's risk oversight function and the Audit Committee's responsibilities, the Board and its committees were not adequately exercising these functions, were causing or permitting the Company to submit manipulated data to the FDA and to issue false and misleading statements to the investing public, and thus the Individual Defendants on the Board were breaching their fiduciary duties; and (2) the Individual Defendants on the Board who were breaching their fiduciary duties were improperly interested in increasing their unjust compensation by seeking shareholder approval of the amendment to the 2018 Plan, which the Individual Defendants serving on the Compensation Committee were improperly administering by rewarding misconduct. The 2021 Proxy Statement further failed to disclose that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using

postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had not been sent to an outside lab, but rather to Dr. Wang, who is a paid consultant, a member of Cassava's scientific advisory board, and receives benefits under the Plan based on Cassava's stock price; (6) Quanterix h pany failed to maintain adequate internal controls. As a result, the 2021 Proxy Statement was materially false and misleading.

476. The false and misleading elements of the 2021 Proxy Statement led to, among other things, the reelection of the Defendants Barbier, Robertson and Scannon, which allowed them to continue to breach their fiduciary duties to the Company. The false and misleading elements of the 2021 Proxy Statement also led the Company's shareholders to approve, on an advisory basis, Dr. Friedmann's and Defendants Barbier's and Schoen's compensation.

477. Under the direction and watch of the Director Defendants, the 2022 Proxy Statement failed to disclose, *inter alia*: (1) contrary to the 2022 Proxy Statement's descriptions of the Board's risk oversight function and the Audit Committee's responsibilities, the Board and its committees were not adequately exercising these functions, were causing or permitting the Company to submit manipulated data to the FDA and to issue false and misleading statements to the investing public, and thus the Individual Defendants on the Board were breaching their fiduciary duties; and (2) the Individual Defendants on the Board who were breaching their fiduciary duties were improperly interested in increasing their unjust compensation by seeking shareholder approval of the amendment to the 2018 Plan, which the Individual Defendants serving on the Compensation Committee were improperly administering by rewarding misconduct. The 2021 Proxy Statement further failed to disclose that: (1) the quality and integrity of the pre-clinical

and clinical data used to support claims of simufilam's efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had not been sent to an outside lab, but rather to Dr. Wang, who is a paid consultant, a member of Cassava's scientific advisory board, and receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result, the 2022 Proxy Statement was materially false and misleading.

478. The false and misleading elements of the 2022 Proxy Statement led to, among other things, the reelection of Dr. Friedmann and Defendant O'Donnell, which allowed them to continue to breach their fiduciary duties to the Company. The false and misleading elements of the 2022 Proxy Statement also led the Company's shareholders to approve, on an advisory basis, Dr. Friedmann and Defendants Barbier's, Kupiec's, and Schoen's compensation.

479. In the exercise of reasonable care, the Director Defendants should have known that by misrepresenting or failing to disclose the foregoing material facts, the statements contained in the 2021 Proxy Statement and 2022 Proxy Statement were materially false and misleading. The misrepresentations and omissions were material to Plaintiff in voting on the matters set forth for shareholder determination in the 2021 Proxy Statement, including but not limited to, the reelection

of Defendants Barbier, Robertson, and Scannon to the Board; approving an amendment to the 2018 Plan; ratifying Ernst & Young LLP as independent auditor for the fiscal year ending December 31, 2021; and the approval, on an advisory basis, of Dr. Friedmann's and Defendants Barbier's and Schoen's compensation.

480. Additionally the misrepresentations and omissions were material to Plaintiff in voting on the matters set forth for shareholder determination in the 2022 Proxy Statement, including but not limited to, the reelection of Dr. Friedmann and Defendant O'Donnell to the Board; approving an amendment to the 2018 Plan; ratifying Ernst & Young LLP as independent auditor for the fiscal year ending December 31, 2021; and the approval, on an advisory basis, of Dr. Friedmann's and Defendants Barbier's, Kupiec's, and Schoen's compensation.

481. The Company was damaged as a result of the Director Defendants' material misrepresentations and omissions in the 2021 Proxy Statement and 2022 Proxy Statement.

482. Plaintiff, on behalf of Cassava, has no adequate remedy at law.

SECOND CLAIM

Against the Individual Defendants for Breach of Fiduciary Duties

483. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

484. Each Individual Defendant owed to the Company the duty to exercise candor, good faith, and loyalty in the management and administration of Cassava's business and affairs.

485. Each of the Individual Defendants violated and breached his fiduciary duties of candor, good faith, loyalty, reasonable inquiry, oversight, and supervision.

486. The Individual Defendants' conduct set forth herein was due to their intentional or reckless breach of the fiduciary duties they owed to the Company, as alleged herein. The Individual

Defendants intentionally or recklessly breached or disregarded their fiduciary duties to protect the rights and interests of Cassava.

487. In breach of their fiduciary duties owed to Cassava, the Individual Defendants caused or permitted the Company to submit manipulated data to the FDA.

488. Additionally, in breach of their fiduciary duties, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and/or misleading statements and/or omissions of material fact that failed to disclose, *inter alia*, that: (1) the quality and integrity of the pre-clinical and clinical data used to support claims of simufilam's efficacy was overstated; (2) the data the Company held out as supporting the efficacy of its product candidates was manipulated; (3) the Company's experiments using postmortem human brain tissue were contrary to a basic understanding of neurobiology; (4) the biomarker analysis for patients treated with simufilam was manipulated to show simufilam was effective in the Phase 2b results; (5) the re-analysis of the Phase 2b results had not been sent to an outside lab, but rather to Dr. Wang, who is a paid consultant, a member of Cassava's scientific advisory board, and receives benefits under the Plan based on Cassava's stock price; (6) Quanterix had not interpreted the biomarker test results for the tests which it had conducted for the Company, nor had it prepared the charts the Company was using in its presentations on simufilam's effectiveness; (7) due to the foregoing, the Company was under an increased likelihood of facing regulatory scrutiny regarding simufilam; and (8) the Company failed to maintain adequate internal controls. As a result of the foregoing, Cassava's public statements touting its partnerships, preorders, and internal controls were materially false and misleading at all relevant times.

489. The Individual Defendants further failed to correct and/or caused the Company to fail to correct the false and misleading statements and omissions of material fact, which renders them personally liable to the Company for breaching their fiduciary duties.

490. Also in breach of their fiduciary duties, the Individual Defendants caused the Company to fail to maintain internal controls.

491. The Individual Defendants had actual or constructive knowledge that they had caused the Company to improperly engage in the fraudulent scheme set forth herein and to fail to maintain internal controls. The Individual Defendants had actual knowledge that the Company was engaging in the fraudulent scheme set forth herein, and that internal controls were not adequately maintained, or acted with reckless disregard for the truth, in that they caused the Company to improperly engage in the fraudulent scheme and to fail to maintain adequate internal controls, even though such facts were available to them. Such improper conduct was committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of Cassava's securities. The Individual Defendants, in good faith, should have taken appropriate action to correct the scheme alleged herein and to prevent it from continuing to occur.

492. These actions were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

493. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Cassava has sustained and continues to sustain significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

494. Plaintiff on behalf of Cassava has no adequate remedy at law.

THIRD CLAIM

Against the Individual Defendants for Unjust Enrichment

495. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

496. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Cassava.

497. The Individual Defendants either benefitted financially from the improper conduct, or received bonuses, stock options, or similar compensation from Cassava that was tied to the performance or artificially inflated valuation of Cassava, or received compensation or other payments that were unjust in light of the Individual Defendants' bad faith conduct.

498. Plaintiff, as a shareholder and representative of Cassava, seeks restitution from the Individual Defendants and an order from this Court disgorging all profits, including from insider transactions, the redemption of preferred stock, benefits, and other compensation, including any performance-based or valuation-based compensation, obtained by the Individual Defendants due to their wrongful conduct and breach of their fiduciary duties.

499. Plaintiff on behalf of Cassava has no adequate remedy at law.

FOURTH CLAIM

Against the Individual Defendants for Abuse of Control

500. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

501. The Individual Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Cassava, for which they are legally responsible.

502. As a direct and proximate result of the Individual Defendants' abuse of control, Cassava has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

503. Plaintiff on behalf of Cassava has no adequate remedy at law.

FIFTH CLAIM

Against the Individual Defendants for Gross Mismanagement

504. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

505. By their actions alleged herein, the Individual Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Cassava in a manner consistent with the operations of a publicly-held corporation.

506. As a direct and proximate result of the Individual Defendants' gross mismanagement and breaches of duty alleged herein, Cassava has sustained and will continue to sustain significant damages.

507. As a result of the misconduct and breaches of duty alleged herein, the Individual Defendants are liable to the Company.

508. Plaintiff on behalf of Cassava has no adequate remedy at law.

SIXTH CLAIM

Against the Individual Defendants for Waste of Corporate Assets

509. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

510. The Individual Defendants caused the Company to pay the Individual Defendants excessive salaries and fees, to the detriment of the shareholders and the Company.

511. As a result of the foregoing, and by failing to properly consider the interests of the Company and its public shareholders, the Individual Defendants have caused Cassava to waste valuable corporate assets, to incur many millions of dollars of legal liability and/or costs to defend

unlawful actions, to engage in internal investigations, and to lose financing from investors and business from future customers who no longer trust the Company and its products.

512. As a result of the waste of corporate assets, the Individual Defendants and are each liable to the Company.

513. Plaintiff on behalf of Cassava has no adequate remedy at law.

SEVENTH CLAIM

Against Defendants Barbier, Burns, Kupiec, Marsman, and Schoen for Contribution Under Sections 10(b) and 21D of the Exchange Act

514. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

515. Cassava, and Defendant Barbier, Burns, and Schoen are named as defendants in the Securities Class Action, which assert claims under the federal securities laws for violations of Sections 10(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 promulgated thereunder. If and when the Company is found liable in the Securities Class Action for these violations of the federal securities laws, the Company's liability will be in whole or in part due to Defendants Barbier's, Burns' Schoen's, Kupiec's, and Marsman's willful and/or reckless violations of their obligations as officers and/or director of Cassava.

516. Defendants Barbier, Burns, Schoen, Kupiec, and Marsman, because of their positions of control and authority as CEO and Chairman, SVP, CFO, CCDO, CMO, and consultant and Senior Vice President of Regulatory Affairs of Cassava, respectively, were able to and did, directly and/or indirectly, exercise control over the business and corporate affairs of Cassava, including the wrongful acts complained of herein and in the Securities Class Action.

517. Accordingly, Defendants Barbier, Burns, Schoen, Kupiec, and Marsman are liable under 15 U.S.C. § 78j(b), which creates a private right of action for contribution, and Section 21D

of the Exchange Act, 15 U.S.C. § 78u-4(f), which governs the application of a private right of action for contribution arising out of violations of the Exchange Act.

518. As such, Cassava is entitled to receive all appropriate contribution or indemnification from Defendants Barbier, Burns, Schoen, Kupiec, and Marsman.

PRAYER FOR RELIEF

FOR THESE REASONS, Plaintiff demands judgment in the Company's favor against all Individual Defendants as follows:

(a) Declaring that Plaintiff may maintain this action on behalf of Cassava, and that Plaintiff is an adequate representatives of the Company;

(b) Declaring that the Individual Defendants have breached and/or aided and abetted the breach of their fiduciary duties to Cassava;

(c) Determining and awarding to Cassava the damages sustained by it as a result of the violations set forth above from each of the Individual Defendants, jointly and severally, together with pre-judgment and post-judgment interest thereon;

(d) Directing Cassava and the Individual Defendants to take all necessary actions to reform and improve Cassava's corporate governance and internal procedures to comply with applicable laws and to protect Cassava and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote the following resolutions for amendments to the Company's Bylaws or Certificate of Incorporation and the following actions as may be necessary to ensure proper corporate governance policies:

1. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the board;

2. a provision to permit the shareholders of Cassava to nominate at least three candidates for election to the Board;

3. a proposal to ensure the establishment of effective oversight of compliance with applicable laws, rules, and regulations;

(e) Awarding Cassava restitution from Individual Defendants, and each of them;

(f) Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs, and expenses; and

(g) Granting such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demand a trial by jury.

Dated: November 6, 2023

Respectfully submitted,

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